PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/41

A1

(11) International Publication Number: WO 99/27863

(43) International Publication Date: 10 June 1999 (10.06.99)

(21) International Application Number: PCT/US98/25827

(22) International Filing Date: 4 December 1998 (04.12.98)

(30) Priority Data:

60/067,460	4 December 1997 (04.12.97)	US
60/085,569	15 May 1998 (15.05.98)	US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications

US	60/085,569 (CON)
Filed on	15 May 1998 (15.05.98)
US	60/067,460 (CON)
Filed on	4 December 1997 (04.12.97)

(71) Applicant *(for all designated States except US)*: THERMOLASE CORPORATION [US/US]; 10455 Pacific Center Court, San Diego, CA 92121–4339 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: TANKOVICH, Nikolai Inanovich [RU/US]; 9361 Stargaze Avenue, San Diego, CA 92127 (US). KOLINKO, Vladimair Grigorievich [RU/US]; 12682 Torrey Bluff Drive, #227, San Diego, CA 92130 (US). FINE, David [US/US]; 109 Lexington Road, Lincoln, MA 01773 (US). MILNER, Thomas [US/US]; Austin, TX (US). FRAIM, Freeman [US/US]; 9 Plymouth Road, Lexington, MA 02173 (US). DIBELLA, Francis [US/US]; 1 Haslett Street, Roslindale, MA 02131 (US). LEFEBVRE, Michael, Joseph [US/US]; 12795 Via Teceto, San Diego, CA 92130 (US).

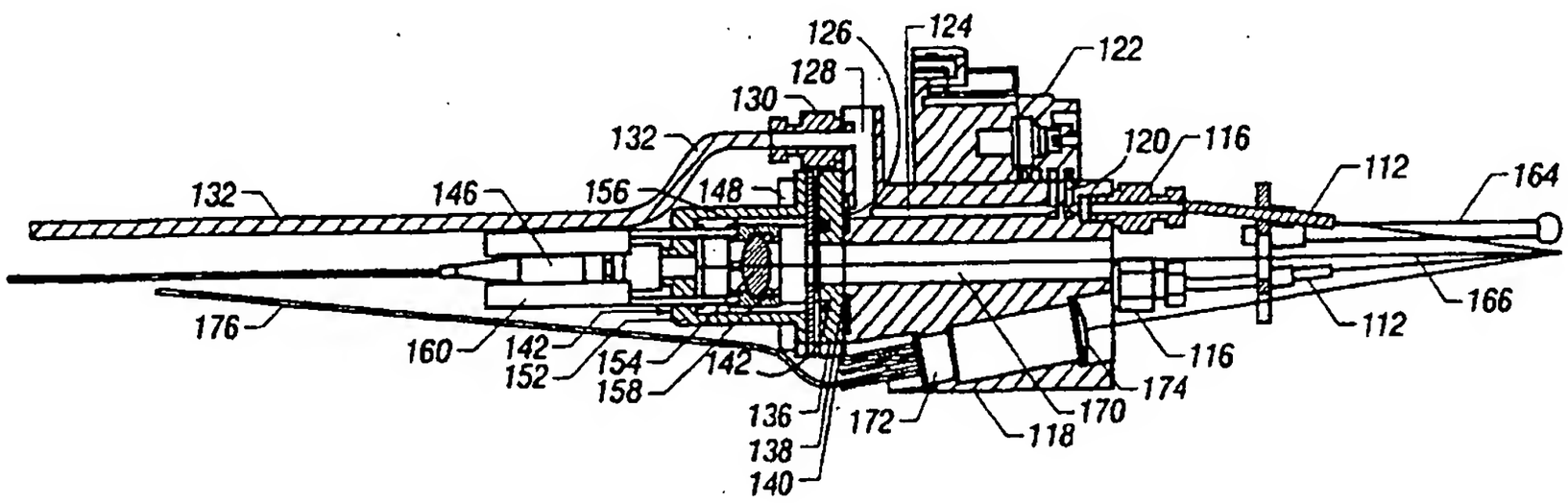
(74) Agent: WAINER, Jonathan, J.; Fish & Richardson P.C., 225 Franklin Street, Boston, MA 02110–2804 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

(54) Title: SKIN COOLING APPARATUS AND METHOD FOR LASER ASSISTED SKIN TREATMENTS



(57) Abstract

A cooling method and apparatus for use in combination with a laser for long–term hair removal and skin peeling. The cooling may be used with such hair-removal or skin peeling, with or without a contaminant that absorbs laser energy. Either concurrently or approximately concurrently with the illumination, the skin surface is cooled so that skin tissue is maintained at temperatures below that which could cause tissue damage. Preferably, the cooling is applied as cryogenic blasts of a cooling medium, e.g. a refrigerant, nitrogen, or cooled air, and may be performed in a cyclical fashion with heating form laser illumination. Optionally, the cooling method and apparatus may be used with an impingement technique and associated device for breaking up the formation of fluid vapor layer immediately above the skin surface for better control of the cooling process.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

SKIN COOLING APPARATUS AND METHOD FOR LASER ASSISTED SKIN TREATMENTS

This invention relates to devices and methods for skin cooling during laser-based skin treatment, including hair-removal and skin peeling.

Background of the Invention

Three techniques for laser-based hair removal are described in the following United States patents: Weissman et. al., Method for Laser Depletion Device and Method, Patent No. 4,388,924; Sutton, Depletion Device and Method, Patent No. 4,617,926; and Mayer, Depilation by Means of Laser Energy, Patent No. 3,538,919. All of these devices and methods are for the removal of hairs one hair at a time with a narrowly focused laser beam. Therefore, they are relatively inefficient and time consuming. U.S. Patent No. 5,059,192 to Zaias, issued October 22, 1991, discloses a process for using a laser beam at a wavelength that is matched to the melanin found at the base of the hair follicle and papilla. An improved laser-based hair removal process is disclosed by Tankovich in U.S. Patents 5,425,728, and 5,226,907 that includes a contaminant in combination with a laser.

Removal of a few surface layer's of a person's skin will generally result in younger looking skin. Recent attempts to remove the skin with a laser have resulted in blistering. U.S. Patent 5,423,803 to Tankovich et al. discloses a process for removal of superficial epidermal skin cells in the human skin without blistering by using a contaminant with laser for relatively gentle skin peeling.

Other types of thermally mediated skin procedures involve the use of a laser. For example, laser treatment of selected hypervascular cutaneous malformations such as port wine stain birthmarks, hemangiomas, and

telangiectasias. These procedures, and also laser hair removal, require photocoagulation of targeted subsurface blood vessels, or damage to hair follicles, while protecting the overlying epidermis from thermal injury. Laser skin peeling, too, can produce thermal effects in the skin and unwanted damage to skin is possible. Cooling may be desirable or even necessary if the temperature of the skin approaches unsafe levels to protect superficial skin structures from undesired thermal injury.

Any of the laser-based skin treatments discussed above, as well as others not discussed would be enhanced by the additional of cooling to prevent damage to non-targeted biological tissue. Accordingly a cooling method and apparatus for use in laser-based skin treatment, which may include hair removal and skin peeling is needed.

It is known to use a low-boiling point refrigerant liquid to cool the skin. However, there is a danger of damaging the skin with this type of coolant. Prior attempts to address the safety issue have typically involved a cyclic method that starts by applying some cooling medium to the epidermis, then applying a pulse of laser light that penetrates the epidermis and heats the dermis, and then cooling the epidermis layer again in attempts to regulate heat transfer and protect the epidermis. A typical first cooling step may cool the epidermis from 36 C to 5 C, and then subsequent cooling attempts apply enough cooling medium to keep the epidermis in this temperature range. with this method it is difficult to heat the target tissue sufficiently to achieve the type of thermal damage desired.

Summary of the Invention

In order to redress the problems discussed above, and those which will become apparent upon reading the description below, the present invention provides a cooling method and apparatus for use in combination with laser-assisted skin treatment, including but not limited to long-term hair removal and skin peeling.

In one optional embodiment of the invention, heating-cooling sequences are used to eliminate or minimize any pain or damage to skin tissue other than tissue adjacent to the hair ducts. Generally in a preferred method heating is followed by cooling and then each is cyclically applied.

Cooling may also be provided in a predetermined timed sequence, such as continuously and possibly concurrent with illumination.

Generally the apparatus of this invention may provide cooling for laser-based skin treatment by application of a cooling medium, such as a cold air blast, or a cryogen-spray. The apparatus of this invention may include a handpiece that provides both optical and cooling capability. In one embodiment of this invention, the combination is used with a dry air circulation system that helps prevent undesirable effects from moisture from air freezing on the skin surface caused by a cryogen-based cooling spray.

In another aspect of the invention, a uniform temperature profile may be maintained in a three-dimensional tissue volume by arrangement of cooling nozzles to achieve control of sub-epidermal depth, and by maintaining control over a two-dimensional skin surface depth.

In still another aspect of this invention, a cryogen storage vessel included with the cooling apparatus is provided with a secondary pressure control

mechanism for further assistance with achieving a uniform temperature profile over a targeted volume of biological tissue.

Another use of this invention is in combination with an Er:glass laser system for the nonablative laser treatment of facial rhytides. The laser operates at a wavelength of 1.54 μm and is preferably delivered to the skin using a fiberoptic handpiece. At this wavelength, the primary tissue chromophore for absorbing the laser energy is water, which has an absorption coefficient of approximately 10 cm^{-1}. The laser delivers a sequence of pulses of light at less than 10 msec duration, and at a 50 Hz repetition frequency and pulse radiant exposures up to 40 J/cm^2.

Preferably, a cryogenic spray cooling device is used to cool the epidermis prior to, and immediately following, laser heating in some aspects of the invention. Such a device uses a multiple nozzle architecture to deliver coolant to the skin surface. The nozzles may be temporally fired in a series of rapid pulses with an appropriate duty cycle which allows the user to tailor a specific temperature depth profile while maintaining an acceptable surface temperature.

Precise timing of the laser heating and cooling pulses may be controlled by computer, and other variables such a fluid flow volume and rate may also be so controlled.

Brief Description of the Drawing

The invention will best be understood with reference to the detailed description below and the drawing figures briefly described below, and in which similar or identical reference numerals describe the same or similar elements:

Fig. 1 is a drawing of a section of human skin showing a growing hair;

Figs. 2A, B, C and D show a cross section of skin and 3 hairs during 4 stages of a process of one embodiment of the present invention;

Figs. 3A and 3B. shows qualitatively the paths of the photons of a laser pulse showing absorption in a carbon-oil suspension;

Fig. 4 A through C shows an experiment with turkey skin, egg white, a partially contaminated hair and a laser beam to demonstrate some of the elements of the present invention;

Figs. 5A and 5B show another experimental set up to demonstrate elements of the present invention;

Fig. 6 illustrates a preferred embodiment providing a photon pathway through hair ducts to the papilla region;

Fig. 7 is a graph showing a preferred illumination-cooling sequence;

Fig. 8 is a simplified-schematic illustration of a cooling system useful for achieving the desired thermal effects of this invention;

Fig. 9 is a simplified-schematic illustration of a handpiece providing optical and cooling functions for use with the cooling system of Fig. 8;

Fig. 10 is a simplifed-schematic illustration of another embodiment of a cooling system useful for achieving the desired thermal effects of this invention with a cryogenic-based evaporative cooling system, and including an alternative hand-held applicator useful for providing cooling and optical functions;

Fig. 11 is a plan (bottom) view of an optical portion of the handpiece of Fig. 10 showing a preferred arrangement of respective nozzles for discharging cooling and dry air spray;

Fig. 12 is another plan (bottom) view of an alternative optical portion for the handpiece of Fig. 10

showing another preferred arrangement of respective nozzles for discharging cooling and dry air spray;

Fig. 13 shows a secondary pressure vessel for adjusting pressure of a cryogen-refrigerant before delivery to the nozzle of the cooling system shown in Fig. 10;

Fig. 14 shows an arrangement of cryogen-spray nozzles for achieving a desired temperature profile including a uniform temperature distribution in a volume of biological tissue;

Figs. 15-20 are views of a multiple nozzle handpiece, in which FIG. 15 is a perspective view, FIG. 16 is a side elevation view of the handpiece without the housing, FIG. 17 is rear end view of the handpiece without the housing, FIG 18 is a section view through line 18-18 of FIG. 17, FIG. 19 is tow plan view of the handpiece without the housing, and FIG. 20 is a front end view of the handpiece without the housing;

Fig. 21 is a schematic of the cryogenic system for use with the handpiece illustrated in Figs. 15-20; and

Fig. 22 is a schematic illustration of a coolant jet directed to a skin surface.

Detailed Description of the Invention

The invention described below includes a cooling apparatus and method useful for any laser-assisted skin treatments, including but not limited to laser-assisted hair removal or skin peeling, and also including other sub-dermal dermatological applications. Although hair-removal is described in detail below as one example of the usefulness of the cooling apparatus and method, one skilled in the art will recognize, in view of the teachings below, that the cooling invention is generally useful for laser-assisted skin treatment, including laser-based skin peeling, as disclosed in the

incorporated U.S. Patent 5,423,803. For purposes of illustrating the cooling invention's applicability to hair-removal, a detailed description of laser hair removal processes is included now.

Human Skin and Hair

A section of human skin showing a cross section of one hair is shown in FIG. 1. The FIG. 1 drawing shows a hair shaft 33, a hair duct 31, a nerve ending 34, a sweat gland 35, a sebaceous gland 38 and arteries 36, veins 37, and papilla 32.

Graphite

In the graphite form of elementary carbon, each carbon atom has three near neighbors and a fourth neighbor at a considerably greater distance away, the two lengths being 1.42 Å and 3.42 Å, respectively. (10,000 Angstroms equal 1 micron.) The network of the three nearest neighbors is planar and extends in the two directions of the plane to the boundaries of the solid. The binding forces between the planes are weak and the planes can slip past each other very readily. For this reason, graphite can be used as a lubricating material. Thin layers of graphite can be removed by abrasion and this property is exploited in the ordinary lead pencil in which motion of the graphite rod over paper causes thin layers of the solid to be rubbed off and spread on the paper. For many years laser workers have used paper thinly coated with small particles of graphite to examine the cross section power of certain laser beams. The energy of many laser beams is readily absorbed by the carbon particles and many of the particles react violently, exploding off the paper and leaving "footprints" on the paper representative of the cross sectional power distribution of the laser beam.

Contaminant

A laser beam absorbing carbon suspension consists of graphite powder in mineral oil. The particle size of the powder is preferably about 1 micron and its concentration preferably is about 20 percent by mass. This suspension is used to contaminate the hair ducts, so we sometimes refer to the suspension as the "contaminant." The expression "contaminant" is also used to refer to the particles of the suspension, as is apparent from the context.

Cleaning

A section of skin with growing hairs is depicted in FIG. 2A. The skin is preferably washed with soap and water then rinsed with water and dried with a cloth towel. The skin section is then cleaned with methyl alcohol and allowed to dry.

Waxing

A next step in this embodiment is to physically remove the hair shafts from the hair ducts in the skin section to be treated. This may be accomplished using a well-known temporary hair removal procedure known as waxing. We prefer using a commercially available wax marketed by Select Spa Source of Sausilito, California under the trade name Nature's Own Pine Wax although a wide variety of such waxes are available and would be satisfactory. We follow the waxing procedure furnished with the wax.

It is believed that removal of the hair from the hair ducts greatly increases the space available in the hair duct for the graphite based contaminant permitting a much greater quantity of the contaminant to be infiltrated into the hair duct. FIG. 2B shows the same three hair ducts as FIG. 2A with the hair shafts removed. Nevertheless, one skilled in the art will recognize that waxing is only an optional step.

Topical Application of Contaminant

The next step is to apply the described graphite-oil contaminant to the section of skin to be treated. The contaminant is applied to the skin in quantities of about one gram per 10 square centimeters, although the exact amount is not critical. The contaminant is massaged thoroughly on the skin surface for a period of about 1-minute for each 10 square centimeters of skin surface. Our principal objective in this step is to cause as much of the graphite particles as feasible to infiltrate into the hair ducts in the skin section. Our tests indicate that our graphite oil contaminant can be infiltrated with this massage technique into the hair duct to a depth of about 0.5 mm. For a 100-micron diameter hair duct, this would correspond to about 700,000 carbon particles in the duct. There is great variation in the amount of graphite infiltrated but we can assume for illustration purposes an infiltration of 700,000 one-micron particles (about 1.4×10^{-6} grams of carbon particles.) At the conclusion of the massaging step, the contaminant is present in the upper part of the hair duct and the skin surface is substantially covered with graphite-oil contaminant as shown in FIG. 2C.

Phases of Illumination

As indicated above the present invention provides a process with at least two distinct phases of illumination with the objective of achieving maximum hair destruction with otherwise minimal damage to skin tissue. In a preferred process the illumination is provided by a Nd:YAG pulse laser operating at a wavelength of 1.06 microns with a beam cross sectional area of about 0.5 cm^2. Controls on the laser permit selection of short pulses of 10 ns duration using a Q switch and a long pulse duration of about 100 microseconds (100,000 ns), with the Q switch

disconnected. (The pulse duration is approximately the interval of time over which the pulses are at least one half maximum power.) Pulse energy can be adjusted to between about 0.1 J and 1.25 J, corresponding to 0.2 J/cm^2 and 2.5 J/cm^2 for the 0.5 cm^2 beam.

Explosion Phase

We refer to the first phase of our illumination process as the "explosion phase" in which particles are exploded. The laser is adjusted to produce about 1 Joule per pulse, which is equivalent to about 2 J/cm^2 since the beam cross section is about 0.5 cm^2. The pulse duration is about 10 ns and the repetition rate is about 10 Hz. Each portion of the skin section to be treated is illuminated with about two to three pulses. This is done by scanning the 0.5 cm^2 10 Hz beam over the skin surface at the rate of about 2 cm/s.

Each pulse contains about 1 x 10^{19} photons. The 1-micron graphite particles are very highly absorptive of the 1.06-micron laser photons. We estimate the absorption coefficient of graphite to be between several thousand to about 100 thousand times greater than the absorption coefficient for typical skin tissue. The penetration depth for 1.06 micron photons in graphite is substantially less than 1 micron so substantially all photons encountering a particle are absorbed by it. The 1.06-micron photons are well scattered by skin tissue. The scatter coefficient for dermal tissue is estimated to be about 100 cm^{-1} whereas the absorption coefficient is estimated to be about 0.33 cm^{-1}. Therefore, the length of the path traveled by photons between scatters is estimated to be about 100 microns and the path traveled in the dermis before absorption in the dermal tissue is estimated to be 3 cm. The result of the large scattering is that the 1.06-micron photon flux builds up and is actually greater (by a factor of about 5) just below the

surface of the skin than the incident flux on the surface of the skin. At two to three mm below the surface (about the depth of most hair roots) the flux has decreased but is still about equal to or maybe a little less than the incident flux. Almost all of the photons entering the skin surface are ultimately absorbed in the carbon or absorbed in the skin tissue.

The cross sectional area of a 1 micron particle is roughly 1 x 10^{-8} cm^2 so the energy absorbed by a typical particle out of a 2 J/cm^2 flux is in the range of about 2 x 10^{-8} J. This is a very small amount of energy but the particle is also very small (with a volume of about 1 x 10^{-12} cm^3). Its density is about 2 gm/cm^3 and its average specific heat is about 2 J/gmC over the temperature range from ambient up to its vaporization temperature. Therefore, each pulse pumps enough energy into the graphite particle to substantially raise its temperature. Graphite vaporizes at about 3,600°C. It is believed that only a portion of the energy absorbed by the particle is used to heat it from 27°C (normal skin temperature) to its vaporization temperature. The remainder of the absorbed energy is released in a miniature explosion of the particle in which a portion of the particle is vaporized and the particle is broken into smaller particles, which recoil away from the explosion site. The explosion also creates a shock or pressure wave, which pushes other particles away from the explosion site. The heat capacity of carbon average about 2 J/gm°C over the range 0 to 3,600°C. The heat content to raise the temperature of graphite to the vaporization point is then about 7,200 J/gm. Thus, in our example (7,200 J/gm) x (2 x 10^{-12} gm) = 1.4 x 10^{-8} J of the absorbed laser energy is used to raise the temperature to the vaporization level. The remaining 0.6 x 10^{-8} J absorbed causes the vaporization of a portion of the

graphite particles. The heat of vaporization of carbon is about 6 x 10^4 J/gm; therefore, the energy needed to vaporize all of the 1 micron (2 x 10^{-12} gm) particle is about 12 x 10^{-8} J. Hence, in this illustration only about 5 percent of the particle is vaporized with each pulse.

One effect of the miniature explosions is to blow essentially all of the particles off the surface of the skin. Some of the particles and portions of particles in the upper parts of the hair ducts are blown out of the hair ducts. Most of the particles in the upper portion of the hair ducts, however, are shielded to some extent by particles surrounding them and are forced further down the ducts by the explosion of particles near the top of the ducts. FIG. 2D shows some typical distribution of graphite particles in the ducts after the conclusion of the explosion. If we assume that the quantity of graphite in the typical duct is roughly 1.4 x 10^{-6} gm (700,000 particles) we can estimate the total energy absorbed in each hair duct. For illustration, if we have 700,000 particles in the duct and assume an average of 2 x 10^{-8} J absorbed per particle per pulse, we would estimate an absorbed energy of about 14 x 10^{-3} J/pulse. This is equivalent to the amount of energy needed to increase the temperature of a cylinder of water 3 mm long and about 67 microns in diameter by 80 degrees C. The estimate could be much higher if we assume greater quantities of particles and if we take into account flux buildup near the skin surface. Skin tissue has a specific heat which is about the same as water. From this illustration we expect that we achieve some damage to skin tissues within a few microns of the upper part of the hair duct during the explosion phase but probably not enough to devitalize the hair. Also, some damage may result from the shockwaves or pressure waves. However, the main advantage of the explosion phase is that particles are forced down

the duct to the region of the duct near the papilla through which growing hair receives its nourishment. The explosion phase also clears substantially all particles off the surface of the skin.

Cooking Phase

First Cooking Phase Embodiment

The second phase of the illumination phase is referred to as the "cooking" or "thermal phase" because the objective of this phase is to heat the skin tissue adjacent to the hair duct to a temperature high enough to permanently devitalize (kill) it, so that the tissue cannot support future hair regrowth. A first embodiment of a cooking phase is described as follows. Prior to starting this phase, graphite particles remaining on the skin surface are cleaned off as completely feasible with a cloth soaked in mineral oil. This also tends to fill in void spaces in the hair duct (especially at the top of the duct) with mineral oil. Mineral oil transmits 1.06 microns light very well. We target a volume within about 150 microns radius of the center of the hair duct. The heating is accomplished primarily by applying heat from laser illumination to the graphite particles, which are now distributed deeply in the hair duct. Laser photon absorbed in the graphite particles include photons scattered into the hair duct from the surrounding skin tissue and also photons transmitted down the hair duct through mineral oil which now fills the upper part of the duct. Heat is transferred by conduction from the graphite to the surrounding tissue. During the "cooking phase" we apply heat energy slowly enough so that we avoid substantial vaporization or fracturing of the graphite. By so doing we can apply heat to the tissue via the graphite particles a very large number of times.

This first heating-cooling embodiment is described in FIG. 7. Two 100-ms, 20J/cm2 Nd:YAG 1.06-micron pulses

are spaced apart by 150 ms, followed after 50 ms by 40-ms skin surface cooling pulse at 0 degrees C, followed after 10 ms by a third 100-ms, 20 J/cm2 Nd:YAG pulse which is followed again after 50 ms by another 40-ms cooling pulse, followed by a similar fourth laser pulse and another cooling pulse and a final fifth laser pulse. With this process about 100 Joules per square centimeter is deposited into the skin without any significant pain or over heating of the skin. However, the bulk of the skin tissue about 2 to 3 mm below the skin surface near the hair follicles is raised from the normal temperature of about 36 degrees C to a temperatures a few degrees below the skin temperature pain threshold and the threshold for tissue damage. Skin tissue within a few 10s of microns of the graphite particles in the hair ducts are being heated by relatively large quantities of laser energy absorbed then conducted away by the graphite particles and also directly by the laser pulses. Therefore, this tissue is heated to a temperature substantially in excess of the threshold for tissue damage. Thus the tissue surrounding the follicle is effectively devitalized without any significant damage to skin tissue in general. Since the volume of high temperature is very small and concentrated there is no significant pain. The cooking phase may be repeated as many times as desired because there is no diminution of the quantity of graphite during this phase. We recommend that the cooking phase be repeated at least 3 times, but to be sure of a good result about 10 repetitions is suggested.

Second Cooking Phase Embodiment

In a second cooking phase embodiment, we disconnect the Q switch so that our laser produces pulses of about 100 microseconds duration with a pulse energy at 2 J/cm^2 and the repetition rate at 10 Hz. In this

embodiment we cool the skin with 0 degree air concurrently with the laser illumination.

The skin is scanned so that each portion of the section of the skin being treated is illuminated for only about 2.5 seconds (about 25 pulses) before moving to another skin section. Each pulse in addition to heating the graphite, applies heat generally to the skin tissue and increases the temperature of the skin tissue about 0.5 to 1.5 degrees C, so more than 30 pulses could cause the skin portion being illuminated to become very warm. In our experiments burning pain is experienced after five to seven seconds of 2 J/cm^2 10 Hz pulses (100 to 140 $Joules/cm^2$); therefore, we limit the number of laser pulses periods to well below this threshold.

Each portion of the skin section being treated receives about 20 scans for a total of about 500 pulses. (This takes a total of about 50 seconds per portion.) Each 1 micron particle absorbs very roughly about 2×10^{-8} Joules per pulse or about 50×10^{-8} Joules per 2.5 second scan. Heat diffuses out from the graphite particles to a distance of about a few tens of microns during the first few milliseconds after the start of a scan and diffuses a few hundred microns in one second. If we assume the equivalent of 500,000 one micron cubic particles per duct, each duct would receive roughly about 0.25 Joule per each 2.5 second scan. This 0.25 Joules would be sufficient to increase the temperature of a volume of water 3 mm long and 563 microns diameter by 80 degrees C. The specific heat of skin tissue is about the same as that of water. Skin tissue is devitalized (killed) if kept at a temperature of 70 degrees C for about 1 second. Skin tissue closest to the carbon particles will be heated to temperatures much higher than 70°C. We estimate that skin tissue within about 1 to 3 hair diameters of the hair ducts is devitalized during this phase. Actual

biopsy studies of both pig and human skin confirm these estimates.

Third Cooking Phase Embodiment

In another embodiment, the second phase illumination consists of about 2,000 pulses at 0.2 J/cm² with a pulse duration of 10 nanoseconds. This requires about 200 seconds per skin section but the cross section of our laser beam can be expanded by a factor of ten and the illumination scan time can be increased from about 3 seconds to about 12 seconds or longer without significant rich general skin burning. At 0.2 J/cm² the particles are heated to temperatures in the range of about 1,000 degrees C. Again, cooling is provided continuously and concurrent with the illumination.

Clean-Up Phase

During a third phase of the illumination process, which we call the "clean up phase", the skin section can be illuminated with about ten Nd:YAG laser pulses at 1.06 micron wavelength and 10 Hz, each pulse having an energy density as in the first phase of about 2 Joules/cm² and a pulse width of about 10 nanoseconds. Again, the pulse duration is so quick that very little heat is conducted out of the particle during the pulse. As before, the power density of these pulses is about 200 Megawatts/cm², enough to heat the particles to over 3,600 degrees C, cause explosions of the particles and vaporize with each pulse a portion (about 5 percent) of the particles. These explosions cause additional damage to the tissue surrounding the particles. Also, after about 10 to 30 pulses, the particles are mostly vaporized or broken into particles so small that they are invisible to the unaided eye. Any remaining particles small enough to be removed by the body's natural cleaning mechanisms.

EXPERIMENT WITH SMALL PARTICLES

In order to confirm the above description of the hair-removal process, we have conducted experiments in which these small carbon particles were irradiated with pulses of the type described above.

Particles in a Bottle

A small number (about 0.1 gm) of one micron size graphite particles were placed in an enclosed glass vial in an air atmosphere and irradiated with pulses as described above under the "Explosion Phases" with no scanning. The particles were continuously broken into smaller and smaller particles and after about 10-15 pulses they vanished. We believe the very small particles were oxidized to form CO or CO_2. When the same experiment is conducted in an argon atmosphere the particles continued to break into smaller and smaller parts until they were nearly invisible to the unaided eye (i.e. about 0.1 micron to 0.05 micron).

Experiment with Fiber Optic Tube Simulating Hair Duct

We have also conducted laboratory experiments to demonstrate the effectiveness of the explosion phase and the cooking phase of the above-described embodiment. In one experiment we infiltrated our carbon-oil contaminant into the top of a 100 micron inside diameter, 5 mm long fiber optic tube to a depth of about 1 mm. We then blocked the bottom of the tube and irradiated the top of the tube with one 10-ns pulse from our Nd:YAG laser at 2 J/cm^2. As a result of miniature particle explosions at the top of the tube, graphite particles were distributed throughout the tube with maximum concentration of particles at the bottom of the tube. We then illuminated the tube with 100 microsecond 2 J/cm^2 pulses for five seconds. The heat absorbed by the carbon caused the inner surface of the tube and tube's fiber clad to deform. A tube without graphite was illuminated with 2 J/cm^2 for 25 seconds with no visible effect on the tube. In another

test of a tube with graphite in it and illumination at 3 J/cm^2 for five seconds the tube melted.

Pig Experiment

In other experiments we tested our preferred process with pig skin in vitro. In one experiment to examine the explosion phase of our preferred illumination process, hairs in sections of the pig skin was removed prior to the topical application of the contaminant and in other skin sections the hair was not removed. After the topical application of the contaminant, the skin sections were illuminated with 1, 2, 5 and 10 pulses (all at 10 ns duration) at power levels of 1 J/cm^2, 2_J/cm^2 and 3 J/cm^2. The skin was then biopsied to permit examination of the follicles. The maximum and deepest contamination was produced with 2 pulses at 2 J/cm^2. At 3 J/cm^2 vaporization of the carbon became substantial. In those sections where the hair was removed the graphite particles completely filled the hair ducts with heavy concentration at the bottom of the duct. In those sections where the hair was not removed, the graphite particles were distributed deeply into the duct, but generally very few particles reached the bottom of the ducts.

Hair in Egg White Experiments

(1) Short-Pulse-High Power

FIGS. 4A, 4B and 4C are sketches illustrating an experiment performed in order to demonstrate elements of this hair removal process. Three layers of turkey drumstick skin 10 were sandwiched between two glass microscopic slides 8. The thickness of the 3 layers of turkey skin was about 2 millimeters (approximate depth below the skin surface of the bottom of human hairs). A single human hair 16 about 10 cm long was coated over a 3 cm section with a mixture 18 of 1 micron particles of carbon (graphite) and mineral oil (about equal mass). The

hair was immersed in chicken egg white 14 contained in a small (5 cm diameter) vial 12. The drawing is roughly to scale except the diameter of the hair and the carbon-oil contaminant is exaggerated.

The hair including the coated section was illuminated with 100 pulses of laser radiation from a Nd:YAG laser.

The following is a description of the pulsed laser beam:

Wavelength	1.06 micron
Energy per pulse	1.5 Joules
Beam area	1/2 cm^2
Energy density	3 J/cm^2
Frequency	10 pulses per second
Pulse duration	10 ns

Each pulse 20 passed through the slides and chicken skin with no apparent effect on the checker skin. The beam also passed through the wall of the vial and through the egg white.

The beam was scanned over the hair so that each portion of the hair received about 5 pulses. The beam had no effect on the hair or the egg white except near the section of the hair which was coated. In that section, the carbon in the mixture absorbed sufficient energy from the beam to cook the egg white immediately surrounding the coated section of the hair. In this experiment we could watch the cooking process because uncooked egg white is transparent.

FIG. 4B shows the result of the first 10 pulses of beam 20 (about 3 pulses into the carbon) passing through the elements of this experiment. The only discernible effect of these pulses was an obvious heating and cooking of the egg white immediately adjacent to the coated section of the hair. Some fragments of carbon particles were thrown off the hair but were trapped in the

immediate surrounding egg white. These fragments were further fragmented by subsequent pulses into very small fragments or oxidized. FIG. 4C shows the results of 100 pulses. The egg white tissue in the immediate vicinity of the coated section was cooked to a thickness of about 500 microns. There was no damage discernible in either the turkey skin or anywhere else in the egg white or to the hair itself other than the coated section. These conclusions apparent to the unaided eye were checked and confirmed under a microscope. Only a very few small particles of carbon remained.

(2) Long Pulse-High Energy

FIG. 5A shows a drawing of another egg white experiment conducted to test the cooking phase. Two layers of chicken skin 50 were placed at the bottom of a glass dish 52. Separate ends of a human hair 54 were glued with "super glue" to paper clips 56 and the portion of the hairs between the clips were coated with a preferred graphite/oil contaminant 58 (about equal mass of mineral oil and 1 micron graphite particles). The hair-paper clip assembly was placed on the chicken skin and the hair, paper clips and skin were covered with egg white. The hair was then illuminated from below through the chicken skin and the egg white with 100 microsecond laser pulses 60 at 2 J/cm^2 at the rate of 10 Hz for about 2 to 3 seconds. This process was repeated several times allowing for cooling between illuminations. With this setup, the experimenter could watch the hot graphite cook the adjacent egg white, and the hair, particles and egg white can be viewed periodically with a microscope. Egg white immediately surrounding the contaminant coated hair was cooked with no damage to the skin or any egg white not close to the contaminant. Also, after many repeat illumination periods of about 2.5 seconds (during which about 50 J/cm^2 was delivered), there was no detectable

diminution of the carbon particles. Therefore, we concluded that the "cooking" process (with in-between cooling periods) could have continued indefinitely with no apparent damage to the skin or egg white except the egg white in the immediate vicinity of the contaminant.

(3) Short Pulse-Lower Energy

The above experiment was also conducted as described above but with pulses at 0.2 J/cm^2 with the Q switch in place so that the pulse was 10 ns and 0.2 J/cm^2. There was cooking of the egg white adjacent to the graphite but no violent explosion or obvious fragmentation of carbon particles. And at the conclusion of a large number of pulses there was no substantial diminution of the graphite particles. At 0.2 J/cm^2 about 250 pulses could be applied before general skin heating would become a problem. With this approach we recommend increasing the pulse frequency to 50 or 100 Hz.

Experimental Conclusion

These experiments show that with 10-ns pulses and 2 J/cm^2 illumination carbon particles explode violently (on a miniature scale) and are partially vaporized. However increasing the pulse duration to 100 microseconds (with pulse energy at 2 J/cm^2) or reducing the energy to about 0.2 J/cm^2 (with a 10-ns pulse) permits delivery of sufficient heat to the carbon to cook tissue with no substantial vaporization or explosion of the carbon. This permits the "cooking phase" to be continued indefinitely.

OTHER EMBODIMENTS FOR HAIR REMOVAL

Buckey Balls

Another potential method of increasing the quantity of contaminant in the hair duct is to use very small spherical particles. A carbon molecule meeting these specifications has recently been produced and is available commercially. These molecules are known as Buckey balls or C_{60}. Buckey balls are carbon molecules,

roughly spherical; each comprised of 60 atoms of carbon. Buckey balls are commercially available, e.g., under the name Buckminsterfullerene from Sigma Chemical Company with offices in St. Louis, Missouri) at prices of about $300 per gram. Our initial experiment with this form of carbon contaminant indicates promising results. The Buckey balls are very absorptive of Nd:YAG laser beams and appear to infiltrate into hair ducts very readily.

Double Application of Contaminant

Another method of increasing the quantity of contaminant in hair duct is to repeat the topical application and explosion phase one or more times. Our experiments indicated that the explosion phase opens the ducts slightly wider providing more room for contaminant on the second application. Increasing the quantity of graphite in the duct increases the amount of heat we can import to the duct during the cooking phase. Steps in one variation of this method would include the following steps:

1. Waxing;
2. First topical application of contaminant;
3. First explosion phase;
4. First thermal phase with skin cooling;
5. Second topical application;
6. Second explosion phase;
7. Second thermal phase with skin cooling; and
8. Clean up phase.

For difficult hair removal cases steps 5, 6, and 7 could be repeated several times. On each repetition, additional graphite accumulates in the hair duct, permitting more and more heat to be imported during the cooking phase. Another approach is the same steps as listed above with the first cooking phase (step 4) omitted. The cleanup phase removes substantially all

graphite from the duct or fractures it into particles of very small sizes.

Mineral Oil Path to the Papilla

In another embodiment, our goal is to deposit graphite particles as close to the papilla as possible and to fill the remainder of the hair duct with mineral oil. We then provide a cooking phase to provide maximum preferential heating of tissue in the papilla region of the hair duct. Steps in one variation of this method would include the following:

1. Waxing;
2. Topical application of contaminant;
3. First explosion phase;
4. Clean skin surface with mineral oil;
5. Apply mineral oil to skin surface and massage into ducts;
6. Thermal phase with skin cooling; and
7. Clean up phase.

We have demonstrated experimentally that mineral oil (being transparent to the 1.06-micron light and having an index of refraction substantially greater than that for skin), will conduct light beams down the hair duct to the papilla area. Thus, absorbers in the papilla region receive illumination both from photons scattered from the dermis and photons traveling through the mineral oil in the upper region of the hair duct. This effect is illustrated in FIG. 6. Note that we have shown the paths of five typical photons A, B, C, D and E. A and B are scattered many times in the dermis and are ultimately absorbed in graphite particles in the bottom of the hair duct. Photon C travels down the hair duct through the mineral oil similar to photons in an optical fiber and also is absorbed in graphite particles at the bottom of

the hair duct. Photons D and E are depicted as being absorbed in skin tissue.

Another approach would consist of the following steps:

1. Waxing;
2. Topical lotion;
3. First explosion phase;
4. Clean skin with mineral oil;
5. Apply mineral oil and massage into ducts;
6. First cooking phase with skin cooling;
7. Second explosion phase;
8. Repeat step 5;
9. Second cooking phase with skin cooling; and
10. Clean up.

Steps 6 and 7 helps clean out and open up the upper portions of the hair duct to permit a cleaner and wider passage for photons through the mineral oil filled hair duct.

VARIATIONS

Persons skilled in the laser-medicine art will recognize that many other light source-contaminant combinations could be used to practice this invention. The important attributes of the combinations are:

1) The light source must penetrate skin tissue, at least for the cooking phase;

2) The contaminant should be capable of being infiltrated in significant quantities into the hair ducts;

3) The contaminant must be very highly absorptive of energy at the wavelength of the beam and capable of being exploded with short high power pulse illumination; and

4) The process includes at least two distinct phases: a) an explosion phase to distribute the particles in the hair ducts and b) a cooking step during which the skin is cooled and heat energy is applied via the contaminant without substantial fragmentation or vaporization of the contaminant.

In addition, a clean up phase is highly desirable in which contaminant remaining in the duct after the cooking phase is vaporized and/or further fragmented into smaller particles by short pulses of light.

The contaminant (e.g., graphite) vaporizes at a very high temperature and during the illumination period of the explosion phase absorbs enough energy to partially vaporize. These circumstances permit the contaminant to transfer high temperature heat to skin tissue and also to provide an explosive force to distribute light absorbing contaminant to the bottom of the hair duct. Ultimate vaporization and breaking into small parts of the contaminant during the clean up phase also serves the useful function of removing most of the contaminant from the duct during the treatment process. Fracturing the contaminant into ever smaller particles is also a satisfactory process of effectively removing the particles. This is because small particles become invisible after a few fractures and once they are reduced to a small fraction of a micron the body's immune system can remove them.

Although particle size is not critical, the particles must be small enough to infiltrate the hair ducts and they should be large enough to absorb the photons. Preferred sizes are preferably in the range of 0.5 microns to about 5 microns. With illumination that penetrates skin tissue about 0.5 cm, no more than about 60 J/cm2 can be added without general overheating of the skin tissue unless a portion of the heat is dissipated.

This overheating can be avoided by applying the heat in increments allowing the skin to cool naturally between illuminations. Another approach is to artificially cool the surface of the skin either prior or during the illumination or both prior to and during the illumination. We have performed tests using cold air, ice and canned nitrogen to cool the surface of the skin. We recommend topical cooling to be used only when natural cooling is not effective. Cooling the surface of the skin may interfere with nerve sensors in the skin, which provide a natural alarm function to prevent unintended damage to the skin.

Many contaminants other than graphite particles in mineral oil may be used. Applicants have tested acrylic tattoo inks which have been approved by FDA for tattoo use. Black and blue tattoo inks marketed by Spaulding and Rogers appear to work well with a Nd:YAG laser operating at 1 Hz, 1.06 micron with an energy density of about 3 J/cm^2. We had less success with other colors.

It is not necessary to remove the hairs prior to illumination. FIG. 3B depicts an illumination phase with the hair shaft remaining in the duct as compared to FIG. 3A where the hair has been removed. The three preferred illumination phases are as described above. The results are not as good with the hair in place during the process since the quantity of graphite which can be loaded into the duct is greatly reduced.

Pulse durations other than those described above may be used. For example, we have performed preliminary tests with 2-ns pulses for the explosion phase. These pulses appear to provide greater explosions but it may be necessary to reduce the energy per pulse to avoid general damage to skin tissue.

We have discovered that better transmission through the skin can be achieved by stretching the skin.

This also helps keep the ducts open which is important when utilizing the embodiment in which photons are transmitted down the hair duct through mineral oil. Pressing the skin reduces the distance between the skin surface and the hair root and could thereby result in more photons being absorbed in the lower regions of the duct.

Illumination during the cooking phase can be affected by any of a wide variety of illumination sources, and with different pulses, from very short nanosecond pulses to much longer pulses, or even a continuous beam for periods of a few seconds. The objective is to impact as much energy as feasible to the graphite particles without causing general overheating of skin tissue. The laser could be controlled with a microprocessor to automatically provide a Q-switched beam, then a non-Q-switched beam followed by a Q-switched beam. Such a system could be useful in conjunction with automated scanning.

Another embodiment of this invention is to utilize for the cooking phase a laser pulse which vaporizes a very small percentage (such as 1%) of the graphite in the duct with each pulse. This would permit several hundred pulses before the quantity of graphite is reduced to the point of ineffectiveness. At that point a few 2 J/cm^2 pulses could be applied to vaporize most of the remainder.

SKIN COOLING

Skin cooling may be used for safely conducting dermatological and cosmetic treatments, such as hair removal, and other skin treatments in general, such as laser-based skin peeling, skin rejuvenation, treating port wine stains, or subdermal skin treatments. Although examples given here for the purpose of teaching how to make and use the cooling-related invention for laser-

assisted skin treatments are primarily concerned with hair removal, and U.S. Patent 5,423,803, which is incorporated herein by reference, relates to laser-based skin peeling, one skilled in the art will readily appreciate that the invention is useful for any type of skin treatment in which lasers are used, including, for example, treatment of spider veins, port wine stains, and such ailments.

The coolant is a low boiling point liquid refrigerant which, when applied, quickly evaporates, thus cooling the surface 50 to 70 degrees Celsius below ambient skin temperature. The coolant is applied as a high speed jet, therefore, the heat transfer coefficient between the liquid and the tissue surface is extremely high, resulting in efficient cooling of the immediate surface and a thin layer below. Surface temperatures remain low enough to maintain epidermal viability, while subsurface tissue temperatures are raised sufficiently high enough by the laser illumination to produce a spatially confined wound to the papillary dermis. The end goal of this modality is to induce a strong wound healing response which results in long term synthesis of new collagen and extracellular matrix material, thus, reducing wrinkles.

In one embodiment, approximately 0 degree C air blown is on the skin surface being illuminated with sufficient force to assure turbulent flow. The turbulence is believed to facilitate evaporization of liquid droplets from the immediate area surrounding the skin.

The methods of cooling available with the cooling systems discussed below with reference to the example of Fig. 7 provide a specific application of the cooling system of this invention, and demonstrate a general method of cooling for safely allowing laser energy to be

used on the skin. One safety concern related to laser-assisted skin treatment is how to protect the epidermis when targeting biological tissue below the epidermis, e.g., the dermis or hair follicles. The general method demonstrated by the example of Fig. 7 involves the step of first applying one or more laser pulses to heat the epidermis and dermis to near the pain threshold (about 50 C), then applying a cooling medium to the epidermis. These steps are followed by the steps of cyclically applying laser pulses and cooling medium so that the target tissue is incrementally heated while the temperature profile of the epidermis is kept cool enough to prevent damage and/or significant pain. The above-described cooling method enables the papillar and subdermal tissue to be heated sufficiently for treatment while protecting the epidermis.

While not wishing to be limited to any particular theory, the invention is believed to be based on a critical recognition that laser light may readily penetrate through the skin to generate heat below, while cooling may be readily applied only to the epidermis. By taking advantage of this principle, not only may the epidermis be protected from heat while heating tissue below, but additionally the epidermis may be protected from excessive cooling because the transfer of laser-generated heat from tissue below to the cooled skin above, maintains a desired safe uniform temperature profile.

Fig. 8 shows an experimental cooling system 23 built and successfully tested for practicing cooling, including capability for implementing the method described above. System 23 includes an air compressor 20 providing compressed air flow through a 3/8-inch 100-foot tube 22 coiled in a large container filled with ice water. Cooled air is released through end 25, preferably

to a handpiece 27 (described in detail below, with reference to Fig. 9) which then releases it to a target region of skin 30. The inventors have also conducted hair removal experiments cooling with ice applied to the skin and with canned nitrogen. Much more sophisticated systems may be used to cool the skin, including using nitrogen or a cryogen-based refrigerant, discussed in more detail below.

Referring again to Fig. 8, the laser beam (not shown) delivered from laser 26 is delivered through optical delivery system 28, such delivery systems being well known in the art. The light, preferably delivered through handpiece 27, illuminates the target skin region 30 in a timed relationship with cooling air from tube 22.

Referring to Fig. 9, system 23 includes a handpiece 27 for delivering both the cooling medium and laser beam. The hand-piece 27 may be coupled with laser system 26 (Fig. 8), directly or indirectly through light-delivery system 28 for delivery of laser beam 60 to the target region of skin 30. The hand piece may also be coupled to one or more cooling-delivery tubes 25a for delivering spray stream 29 of a cold medium to the same target region of skin. The handpiece may also be used with more sophisticated systems and may be varied if needed to add other functions.

The handpiece includes an optical portion 31, a cooling portion 33 that includes coupling piece 37. Optical portion 31 includes one or more well-known laser-matched optical lens (not shown) in an optical cavity (also not shown) for delivering laser beam 60 to the target skin region 30. The optical portion is provided with a tubular coupling piece 34 which fits into bore 36 of cooling portion 33, which includes one or more nozzles 33 for passing cooling spray 29 from tubes 25a to the

target skin region 30. The hand-piece 27 should be spaced a predetermined distance *d* from the skin. Preferably this distance should not exceed 85 millimeters.

Fig. 10 shows a cryogen-based evaporative cooling system 23b which may be also be used to provide effective cooling laser-based skin treatment. Cryogens are non-toxic, fluoroethane-based refrigerants that have been approved as replacements for chlorofluorcarbons. A well-known Cryogen known as Refrigerant 134a, is composed of 100% Tetrafluorothane, and it is a good choice because it has a boiling point of 126 degrees C and a vapor pressure of 72 psia at 18 degrees C.

The cryogen may be administered from storage 40, which may include an optional subcooler, and then sprayed 29b via a fluid atomizing orifice 42 which may be a nozzle injector and that is maintained on handpiece 27 at the fixed distance d above the skin surface 30. Handpiece 27 is similar to handpiece 27b, and is shown on an exaggerated scale for the sake of clarifying the handpiece components. Storage 40 may include a compressor and other necessary known mechanical devices (not shown) for storing, subcooling, and delivering the cryogen. The Cryogen may be atomized in controlled spurts of fluid 27b lasting a predetermined time, e.g, about 40 milliseconds to provide cooling of the type called for in the example shown in FIG. 7.

Pressurized fluid atomizers may be used or alternatively spinner-type atomizers could produce a stream of atomized fluid particles whose diameters can be controlled by adjusting the spin speed. The simplest type of atomizer is probably a very long micro-diameter filament tube, which can be controlled simply by opening a micro-tube at appropriate times during treatment, as described below with reference to FIG. 10.

Referring again to Fig. 10, cooling system 23b comprises a cryogen-based evaporative cooling system that is an effective means of protecting the skin during laser treatments, including hair removal and skin peeling treatments. Evaporative cooling is believed to be the primary mode of heat transfer for safe cooling of the skin surface while using system 23b. The atomization of the cryogen and the adiabatic absorption of some of the liquid into the air directly above the treated area also results in the sensible cooling of that air to between about -60 to -50 °C, which also assists in the cooling of the treated area.

It is believed that the expansion cooling of the stream of spray 29 is due to de-pressurization of the fluid as it exits nozzle 42 mounted to coupling piece 37. Nozzle 42 preferably receives its input from distribution manifold 39. Throttling, or de-pressurization, of the pressured cryogen, or liquid cooling fluid, to atmospheric pressure is a thermodynamic phenomenon that results in the cooling of the exiting fluid as it separates in a two-phase (vapor and liquid) mixture. It is believed further that the skin surface or epidermal layer 30 is sub-cooled via evaporative cooling of the preferably atomized cryogen liquid that reaches the surface. This evaporative heat transfer may be enhanced by maintaining an impingement of the atomized liquid stream that will breakup any formation of a fluid vapor layer above the surface, and in particular such a vapor layer having low thermo-conductive properties. By maintaining a cold skin surface and surrounding environment, the dissipation of laser-generated heat from the epidermal sub-layers via conduction heat transfer will be enhanced.

It is believed that enveloping the affected skin surface by a continuous stream of dry, sub-cooled air 34

will maintain desired thermal effects for the skin and the surrounding environment. An air curtain 34 is applied over the treated surface 30 through delivery orifice 43, which also may be a nozzle, and which like delivery orifice or nozzle 42 also receives its input from distribution manifold 39 coupled to respective feed tubes. Delivery tubes 43t and 42t delivering the dry air spray and cryogen, respectively, to a manifold 37 for respective delivery to nozzles 43 and 42. Laser beam 60, dry air spray 29b, and cryogen spray 60 are delivered in a relatively-timed fashion to maintain a desired temperature profile on target region of skin 30.

The dry air spray 44 forming the air curtain over the treated surface is composed of circulating dry air that is delivered from air circulation device 45 which preferably includes a drying desiccant material 47. The dry air captured in the cryogenic spray stream 29 is cooled by the evaporation of some of the fluid particles exiting the atomizer. The circulating air insures that the cryogen that has been evaporated at the skin surface by the laser-generated heat is immediately removed from the treated surface.

Referring also again to FIG. 9, this removal may be facilitated by the use of a distribution of small vacuum tubes 101 that evacuate the treated surface. This may also serve to recover the cryogen via a liquid coalescer (not shown) if required or desired. The vacuum tubes 101 also provide a necessary fixed height adjustment that should be maintained between the nozzle 42 and the treated surface. Maintaining a constant, predetermined height of the nozzle over the treated surface additionally ensures that the laser beam will be properly focused ont he treated surface. An air collection fixture or "hood" (not shown) and mini-induction blower (also not shown) could also be

incorporated into the integrated design to help recapture the evaporated cryogen fluid rather than allowing it to be released into the air.

The atomizing fluid orifice or nozzle 42 may be a pressurized fluid injector, or may be a spinning disk-type atomizer, that in a simple form is a very small diameter, but relatively long, filament tube in which flow has been restricted to establish a desired flow rate.

It is believed that a pressurized fluid atomizer will instantly produce a cooler, two-phase fluid stream with about 70% of the fluid in the liquid phase and available for evaporative cooling. Controlling the distribution of the atomized fluid particles and removing the ineffective vapor phase of the expanding cryogen will probably improve the overall effectiveness of the evaporative cooling method by at least allowing more controlled predictable responses.

The spinning disk-type atomizer is more complicated than a pressurized fluid injector but provides an advantage of producing a similar stream of atomized fluid particles having particles of a size which can be controlled by simply adjusting the atomizer's spinning speed (rotations per minute). Further a spinning disk-type atomizer may allow for increasing the amount of liquid phase cryogen available for evaporative cooling. It is believed that as the cryogen fluid expands through the nozzle or valve orifice it can be made to impinge on a rotary disk that absorbs energy from the cryogen fluid. This energy removal is believed to increase the amount of liquid fluid percentage in the expanding fluid steam. Thus, the typical 70% fluid amount may be increased to 75%, for example, to provide more liquid at the surface of the skin, and thus faster evaporative cooling.

The nozzles 42 and 43 can be paired in a radially-disposed fashion on coupling piece 37 as shown in the plan (bottom) view of Fig. 11. Of course, the nozzles may be disposed in a number of fashions other than those shown. The schematic view of Fig. 10 shows only one of each nozzle type, with each respective pair-mate not being visible.

Fig. 12 shows an alternative arrangement of the nozzle 42 and 43 relative to coupling piece 37, wherein the orifice 43o of nozzle 43 is larger than the orifice 42o of nozzle 42 which provides an alternative way to ensure that the cryogen spray is enveloped in a dry air curtain. Of course, one skilled in the art will recognize that the geometric relationship of the nozzles may be varied from that shown without deviating from the spirit or scope of the invention.

Referring again to Fig. 10, a temperature detector 50, which in a preferred embodiment is well-known infrared detector is used in combination with temperature control system which may be a well-known digital computer. The skin temperature monitoring may also be performed by thermocouples or resistance temperature detectors that are wired to the underside of a vacuum tubes 101 (FIG. 9) and thus may be in direct contact with the treated surface.

The control system 52 serves as a safety-switch to prevent overheating the skin to dangerous levels. The temperature control system 52 may be used to shut off the laser or otherwise adjust the laser energy-level and/or by applying coolant. Further, the temperature detector 40 and control system 52 can be used to monitor and react to dangerously low skin temperature as well.

The systems described above can be integrated into a light-weight small hand-held instrument 27b that includes the temperature detector 50 communicatively-

coupled to a control system, an optical cavity for passing the laser-beam to the skin, and orifices for delivering cryogenic and dry air sprays. The relatively timed fashion delivery of the laser and cryogenic and dry air sprays may be controlled by a the temperature control system which preferably has computing capability for communicating with the laser for digital control and to the dry air and cryogen systems (e.g. by opening and closing switches and activating valves).

Fig. 14 shows another arrangement of cryogen delivery nozzles 42c in which two features are available. The nozzles are arranged so that their respective stream paths cross, creating turbulence at the confluence 61. This turbulence causes liquid drops to evaporate in the turbulent flow so liquid does not condense on the skin surface. Sufficient turbulence may obviate the need for dry air, or the dry air may be used in a supplemental fashion.

The various arrangements discussed above, allow a desired temperature distribution to be obtained and then maintained by careful arrangement and selection of spray orifices and spray ingredients, and careful synchronization of the laser with cooling. In general the inventors have recognized that pressure, temperature, and nozzle geometry, including orifice geometry are variables that may be manipulated to achieve a desired uniform temperature profile. For example, referring again to Fig. 14, a desired temperature profile may be maintained along lateral dimension "l" and through depth d_t of the skin target region 30. Further, by implementing the teachings of this invention a desired temperature profile may be maintained all through the volume defined by the area bounded by skin of length "l" with depth d_t and width "w." These benefits can arise from employing a temperature control system, effectively minimizing or

eliminating condensation, and controlling the variables described above with reference to the nozzle geometry, and temperature and pressure of the sprays" Moreover, a uniform temperature profile may be maintained along the same volume, such that approximately only one constant temperature can be measured anywhere in the volume.

In recognition of the importance of being able to manipulate pressure, a secondary pressure vessel 66 shown in Fig. 13 and joined by a coupler such as valve 64 to cryogen storage and feed system 40 which includes primary pressure vessel 62. Typically, cryogens stored and are provided at a set nominal pressure (e.g. 72 psia), but the introduction of the secondary pressure vessel 66 allows for the cryogen spray 29 to be delivered at a desired pressure for achieving the desired temperature profile.

NONABLATIVE LASER TREATMENT OF FACIAL RHYTIDES

Another use of this invention is in combination with an Er:glass laser system for the nonablative laser treatment of facial rhytides. The laser operates at a wavelength of 1.54 μm and is preferably delivered to the skin using a fiberoptic handpiece. At this wavelength, the primary tissue chromophore for absorbing the laser energy is water, which has an absorption coefficient of approximately 10 cm^{-1}. The laser delivers a sequence of pulses of light at less than 10 msec duration, and at a 50 Hz repetition frequency and pulse radiant exposures up to 40 J/cm^2.

A cryogenic spray cooling device is used to preferentially cool the epidermis prior to, and immediately following, laser heating. The device uses a multiple nozzle architecture to deliver coolant to the skin surface. The nozzles may be temporally fired in a series of rapid pulses with an appropriate duty cycle which allows the user to tailor a specific temperature

depth profile while maintaining an acceptable surface temperature.

A multiple nozzle laser handpiece capable of spraying a fluid coolant in a temporal sequence through the multiple nozzles is shown in FIGS. 15-20. Referring first to Fig. 15, the handpiece 110 includes three cryogenic nozzles 112 at a distal end. The three nozzles 112 are configured to direct a stream or spray of a fluid cryogen in lines that intersect at a preselected working from a skin surface. Handpiece 110 also includes a thermally insulating housing 114.

Referring now also to Figs. 16-20, each of nozzles 112 are supported by a nozzle fitting 116 that is attached to an aluminum block manifold 118. Manifold 118 includes forward coolant channels 120, each connecting between a respective nozzle fitting 116 and an outlet of a respective solenoid valve 122. An inlet of each solenoid valve 122 is coupled through a respective rear coolant channel 124 an annular channel 126 at a rear end of manifold 118. Annular channel 126 connects to an inlet channel 128, which is coupled through a rear coolant fitting 130 to a coolant inlet tube 132. Tube 132 is coupled to a source of liquid refrigerant, such as Refrigerant 134a, which is provided under pressure. Thus, each of solenoid valves 122 and nozzles 112 are fed through a common coolant line 132 connecting to handpiece 110. Each of solenoid valves 122 also has connected to it respective electrical control signal wires 134, only some of which are shown in the drawing (See Figs. 17 and 19).

In the described embodiment, solenoid valves 122 are provided by SMC Pneumatics, part no. VQ110-5L-M5. These valves are capable of opening and closing is a period of about 2-10 msec. They are operated in a temporal sequence, each with a duty cycle that is short

enough so that its operation is not significantly impaired by cooling. The major benefit of operating valves 122 in a temporal sequence is that short bursts of coolant can be directed at the skin in a rapid sequence not possible using a single valve. the short, rapid bursts avoids pooling of the coolant on the skin. Pooled cold refrigerant on the skin can cause water to condense from surrounding air and ice crystals to form. Ice crystals or liquid water forming on the skin can absorb a significant amount of the energy from the laser beam, and can also distort the focus of the laser beam. Thus, by avoiding pooling on the skin, the negative effects of water condensation and ice formation can be avoided.

Annular channel 126 has a rear wall provided by a forward side of a circular washer 136. Resilient o-rings 138, 140, which are made of neoprene, provide seals between manifold 118 and washer 136. Coupled to a rear side of washer 136 is a lens holder assembly 142. A fiber optic cable 144 is coupled to lens holder assembly 142 through a fiber optic connector 146, which in the described embodiment is an SMA 905 connector. Fiber optic cable 144 couples at its other end to a light source, such as an Er:glass laser or a Nd:YAG laser as described above. Lens holder assembly 142 is screwed to manifold 118 with screws 148 that pass through apertures in washer 136. There is another neoprene o-ring 150 between washer 136 and lens holder assembly 142, allowing adjustment of a tilt angle alignment of lens holder assembly 142 relative to manifold 118 by variably tightening screws 148. O-ring 150 also provides resiliency for compensating for vibrations and the like.

Lens holder assembly 142 includes a housing 152 providing a central chamber. A spherical bi-convex lens 154 is held in place in housing 152 chamber between an outer lens holding ring 156 and an inner lens holding

ring 158. Outer lens holding ring 156 has a threaded outer surface to screw a threaded inner wall of housing 152. Inner lens holding ring 158 also has a threaded outer surface to screw into a threaded inner surface of outer lens holding ring 156 with lens 154 in between. A spanner wrench 160, shown in Fig. 18, fits in slots 162 provided in housing 152 to adjust the longitudinal position of outer lens holding ring 156 within housing 152, and thereby the position of lens 154. By this means, the focal position of a laser beam 166 passing through lens 154 is be adjusted. The lens is locked with a set screw 178. The laser beam 166 passes through a central passageway 170 in manifold 118.

A stand-off 164 is provided at the forward end of handpiece 110. By keeping a forward tip of stand-off 164 touching the surface of a subject's skin, the operator can be assured that the laser beam 166 is focused to the proper depth and the coolant is directed to a spot on the skin illuminated by the laser beam 166. In the illustrated embodiment, stand-off 164 is held by a flange 168 attached to nozzles 112. In another embodiment (not shown) a stand-off is attached to a ring that screws onto a forward end of housing 114.

Handpiece 110 also includes a temperature sensor 172 held in manifold 118. This can be provided, for example, by Eltec Co. part no. 40612. A plano-convex lens 174 directs infrared radiation from the skin onto a receiving surface of sensor 172. Signal wires 176 extend through a cable from the rear of sensor 172.

Referring now to Fig. 21, a coolant fluid system includes a tank 180 holding the coolant 182 in liquid form under pressure. Pressure is maintained by a temperature controller 184 that is coupled to a tank temperature sensor 186 and a heater 188 wrapped around tank 180. The liquid level is monitored with a tank

weight sensor 190. A pressure transducer 192 monitors pressure in tank 180 and provides a pressure signal to a pressure alarm controller 194. If the pressure exceeds a set value, pressure alarm controller shuts off power passing through a first solid state switch 196. Similarly, temperature controller 184 will shut off power passing through a second solid state switch 198 in series with the first switch 196 if the temperature in tank 180 exceeds a set value.

Precise timing of the laser heating and cooling pulses may be controlled by computer. Key modality parameters may be varied including number of cooling pulses, cooling duration and duty cycle time, temporal delay between heating and cooling pulses, and radiant laser exposure. In addition to providing timing signals, such a computer may also monitor various cooling safety interlocks including; optical pyrometer signal to measure surface temperature, flow sensors to insure cryogen delivery and laser control signals to insure laser delivery.

Liquid cryogen is supplied to handpiece at about 90 psig, which is sufficient to prevent boiling in the supply line from the tank to the handpiece. the time between pulses for each valve can be varied between 1 and 20 msec. High heat transfer rates over a short time interval are achieved due to the high velocity of the jet on the surface producing a thin boundary layer, and as a result of a sufficiently high transfer coefficient between the surface and the liquid/gas stream flowing across it.

Referring now to Fig. 22, at the center of a jet 200 the velocities are high, so the heat transfer leads to rapid cooling. Further from the center the velocities slow down, and the boundary layer thickens. If enough fluid flows across the surface the result is a time

interval of low heat transfer rate following the initial high rate period, with a substantial increase of the time cooling occurs due to the pooling of the liquid in the thicker boundary layer. The low heat transfer period will continue until the pooled liquid is evaporated. Cooling with 5 msec pulses with 5 msec spacing over a 50 msec time period can eliminate the pooling and the low heat transfer characteristic. A laser treatment for hair removal, skin peeling, subdermal skin rejuvenation or the like can be carried out as described above with reference to Fig. 7 with handpiece 110 enabling the use of a temporal sequence of rapid fire cooling pulses within the boundaries of each cooling step illustrated.

Thus, it has been shown that this invention offers cooling methods and devices not available before for safely maintaining a desired temperature profile of skin while using a laser-assisted skin treatment, including, but not limited to, long-term hair removal and skin peeling.

The above-described methods are exemplifications of preferred embodiments of the inventions and other possible variations are within its scope. Accordingly, the invention is limited only by appended claims and their equivalents.

CLAIMS

1. A handpiece for laser skin treatment, comprising:

an optical coupling to an illumination source;

a focusing system for focusing illumination from the illumination source to a target region of skin;

a fluid coupling to a coolant fluid source;

a plurality of valves having inputs in fluid communication with the coolant fluid source through the fluid coupling, each valve including an output communicating with a respective nozzle which is arranged to direct the coolant fluid to the target region of skin, the valves operating in a temporal sequence.

2. The handpiece of claim 1, wherein the temporal sequence is characterized in that no two of the valves are open at the same time.

3. The handpiece of claim 2, wherein the temporal sequence is further characterized in that each valve remains open for a period between about 2-10 msec.

4. The handpiece of claim 3, wherein the temporal sequence is further characterized in that there is a period of between about 1-10 msec between the closing of one valve and the opening of a next valve in the temporal sequence.

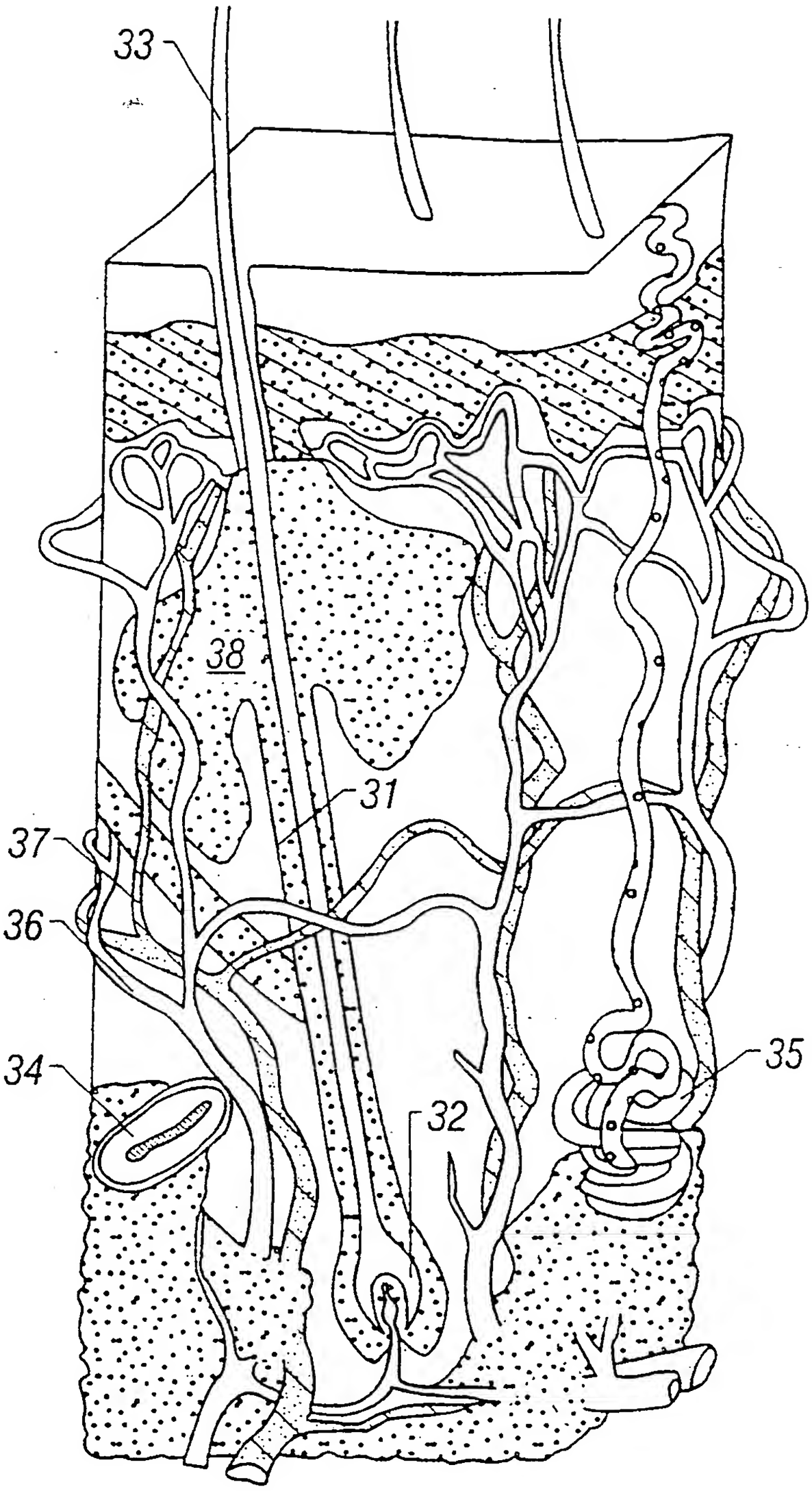


FIG. 1

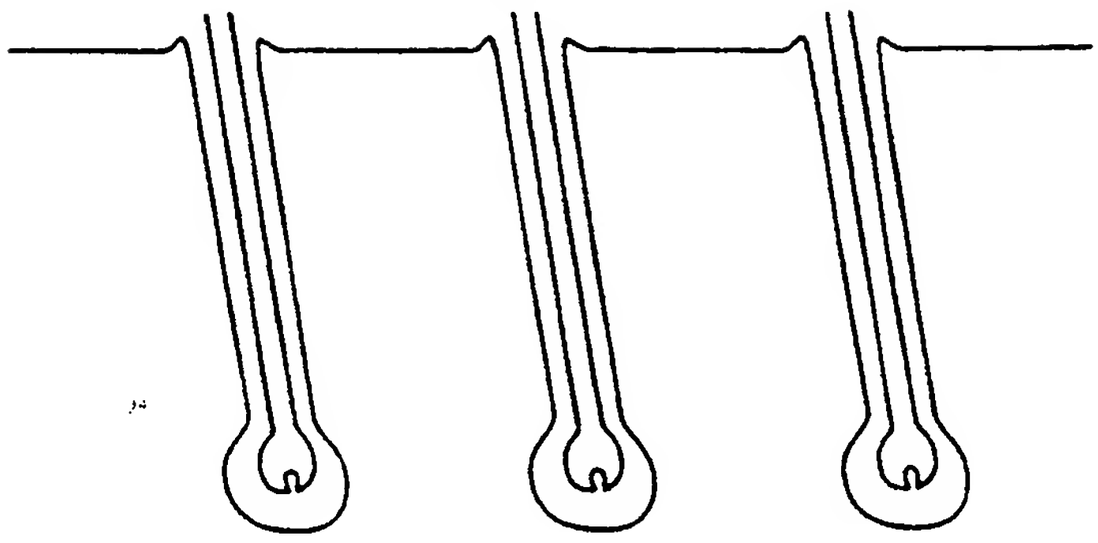


FIG. 2A

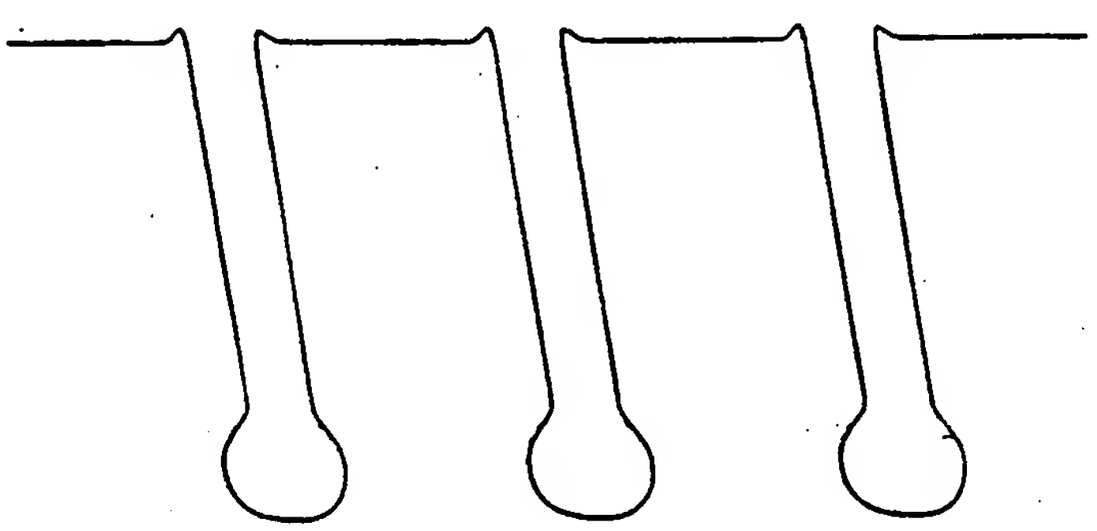


FIG. 2B

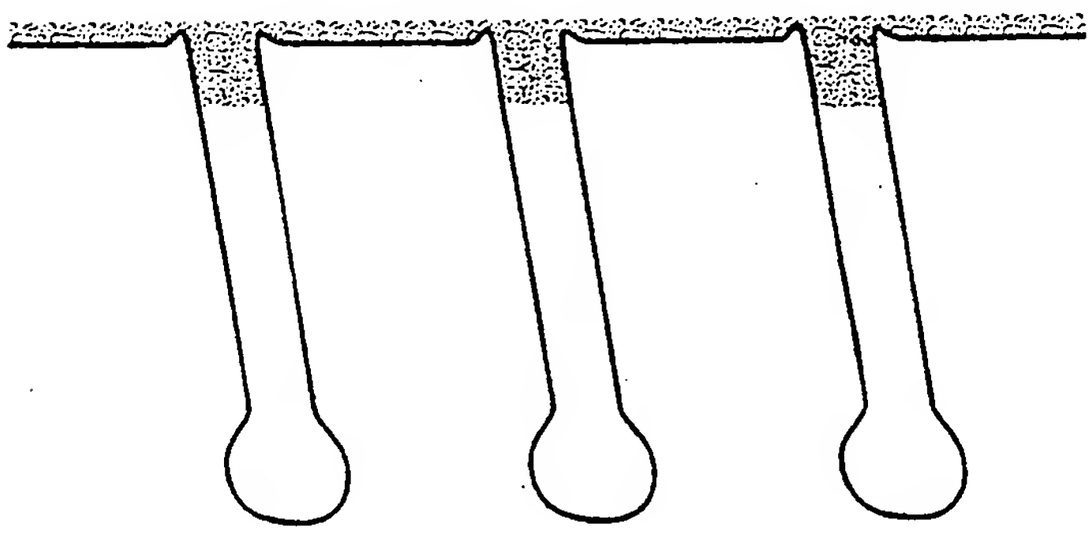
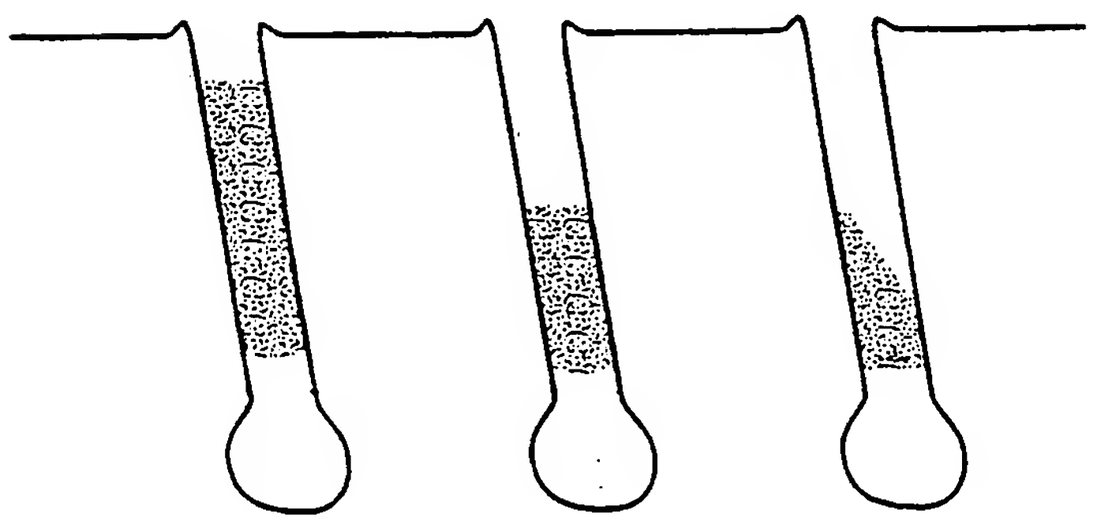


FIG. 2C



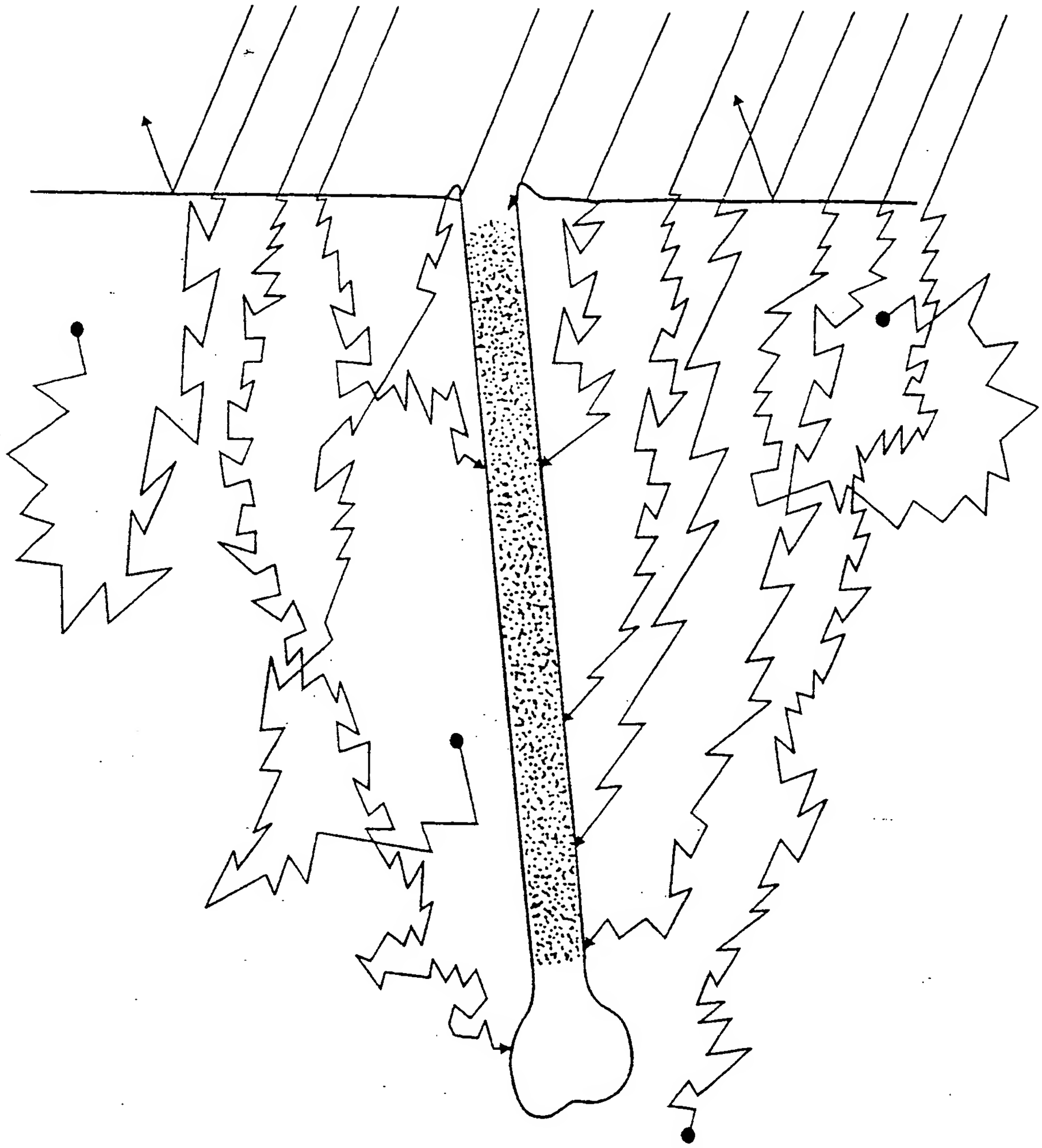


FIG. 3A

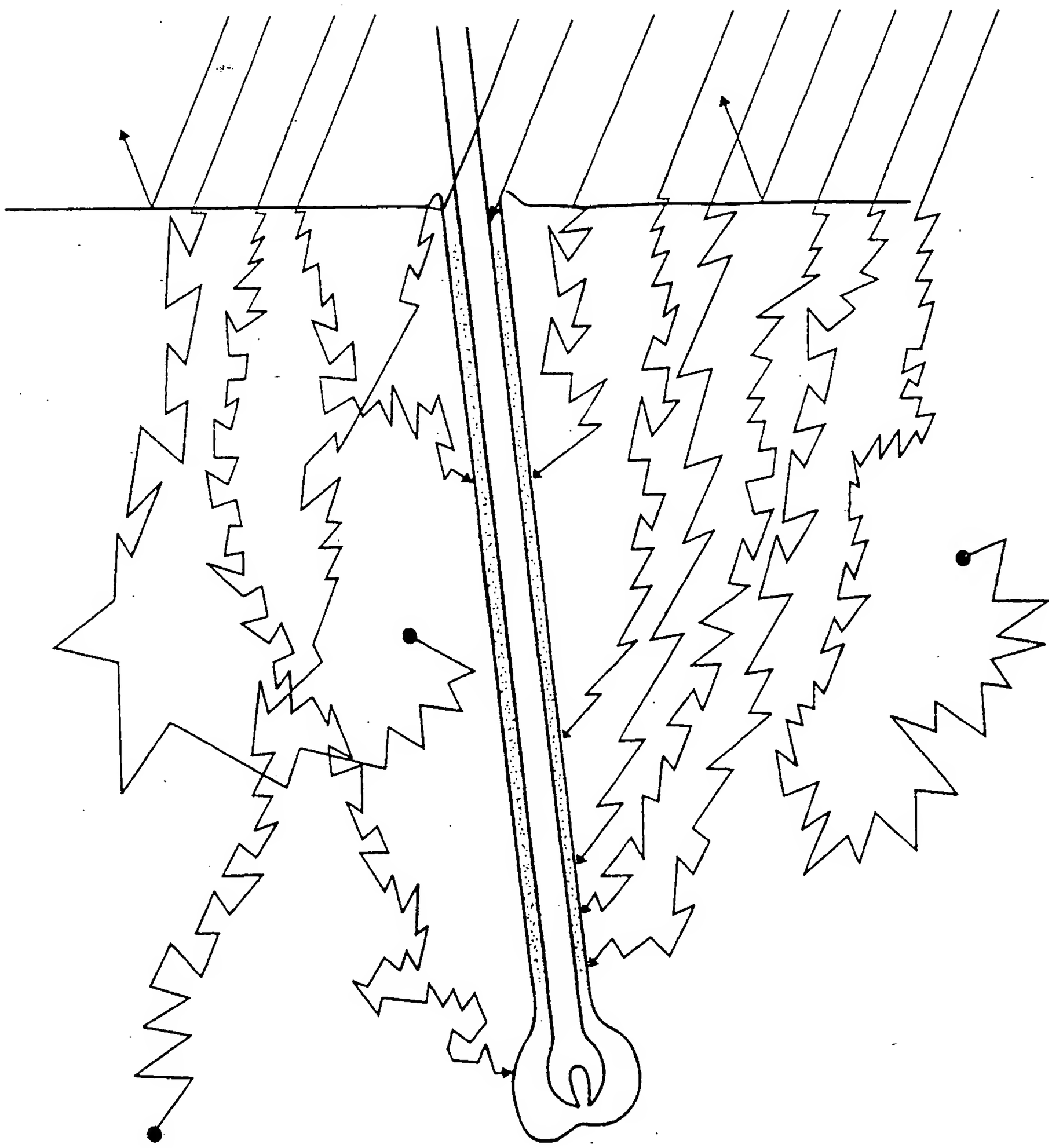


FIG. 3B

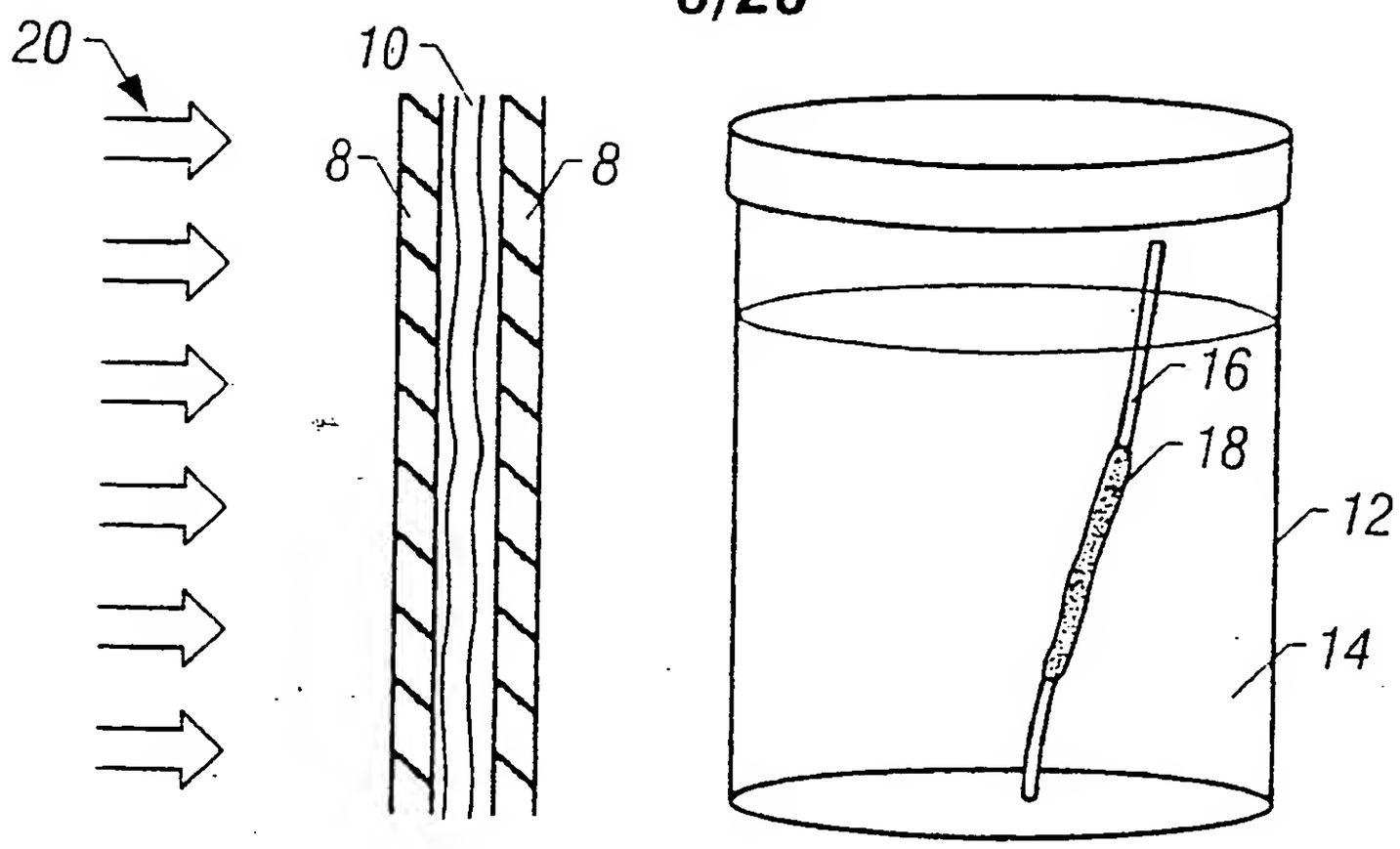


FIG. 4A

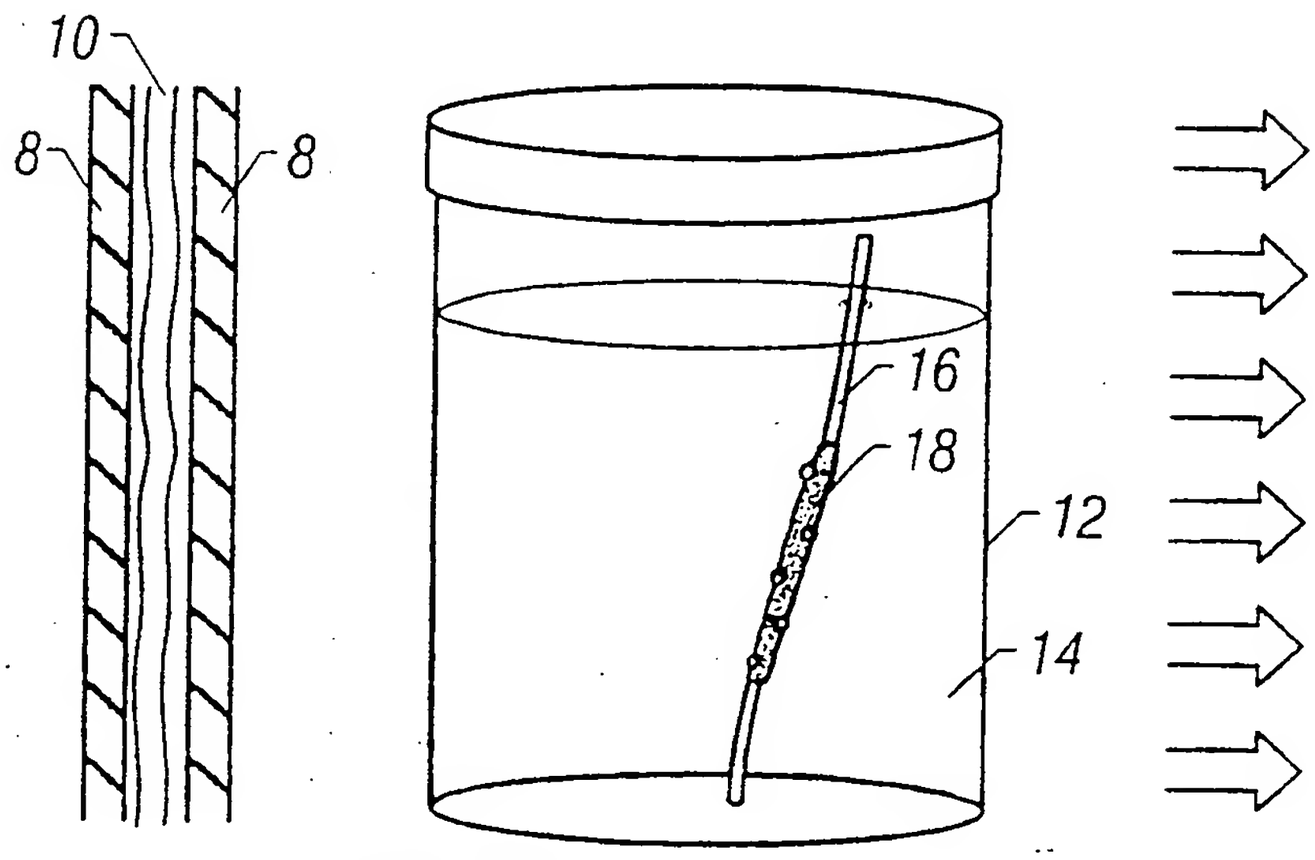


FIG. 4B

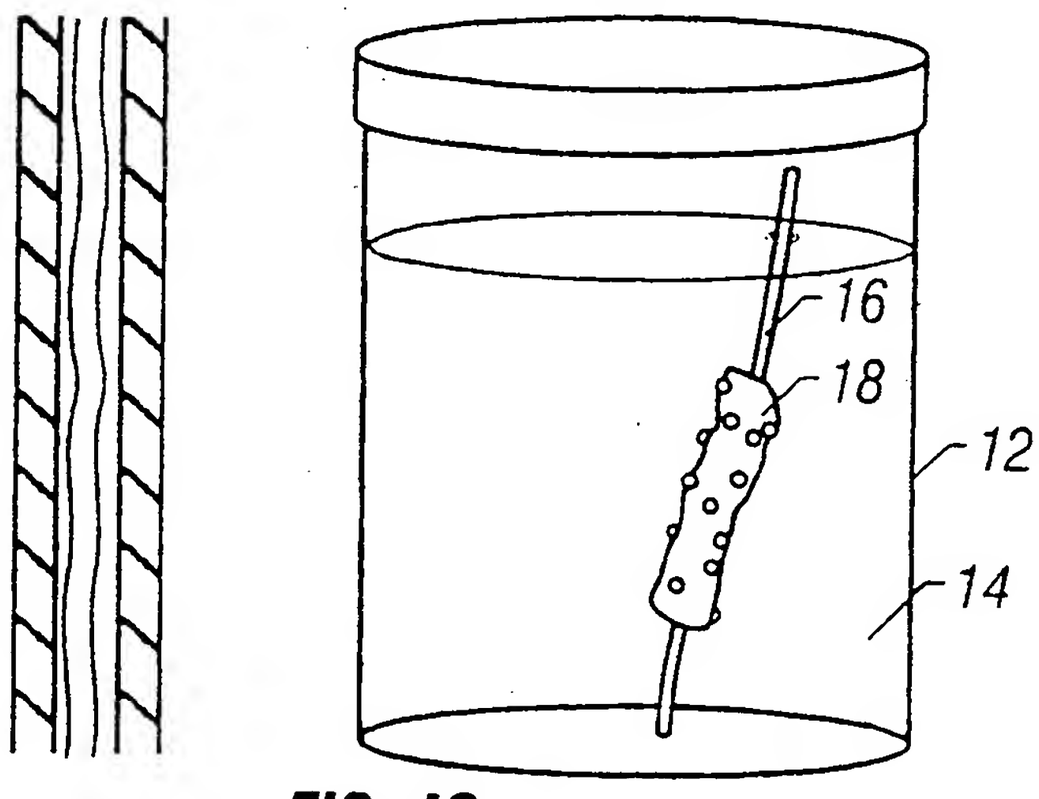


FIG. 4C

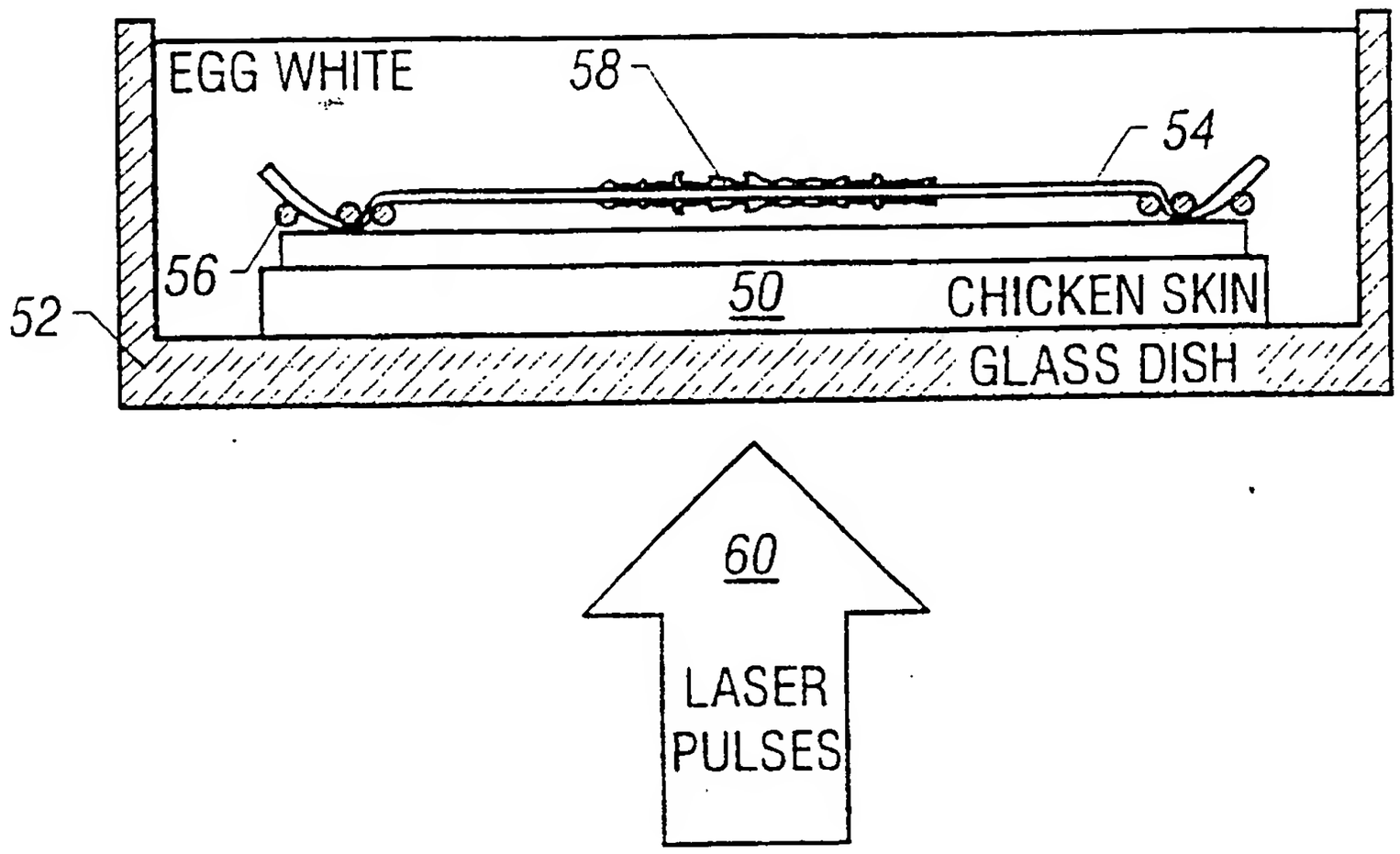

EGG WHITE
58
54
56
50
CHICKEN SKIN
52
GLASS DISH
60
LASER
PULSES

FIG. 5A

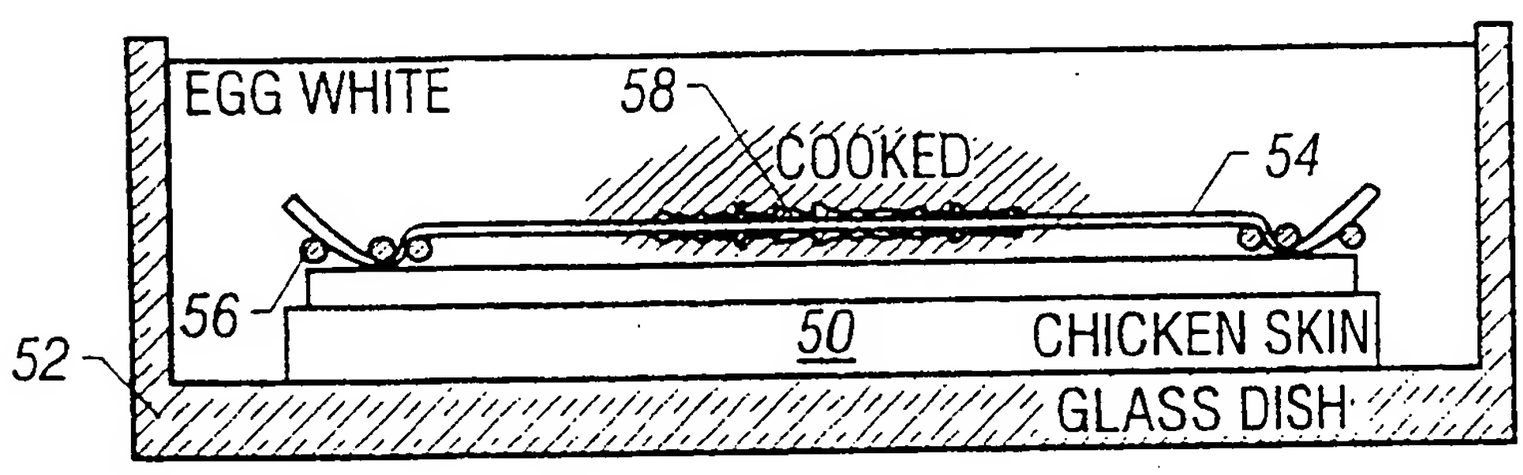

EGG WHITE
58
COOKED
54
56
50
CHICKEN SKIN
52
GLASS DISH

FIG. 5B

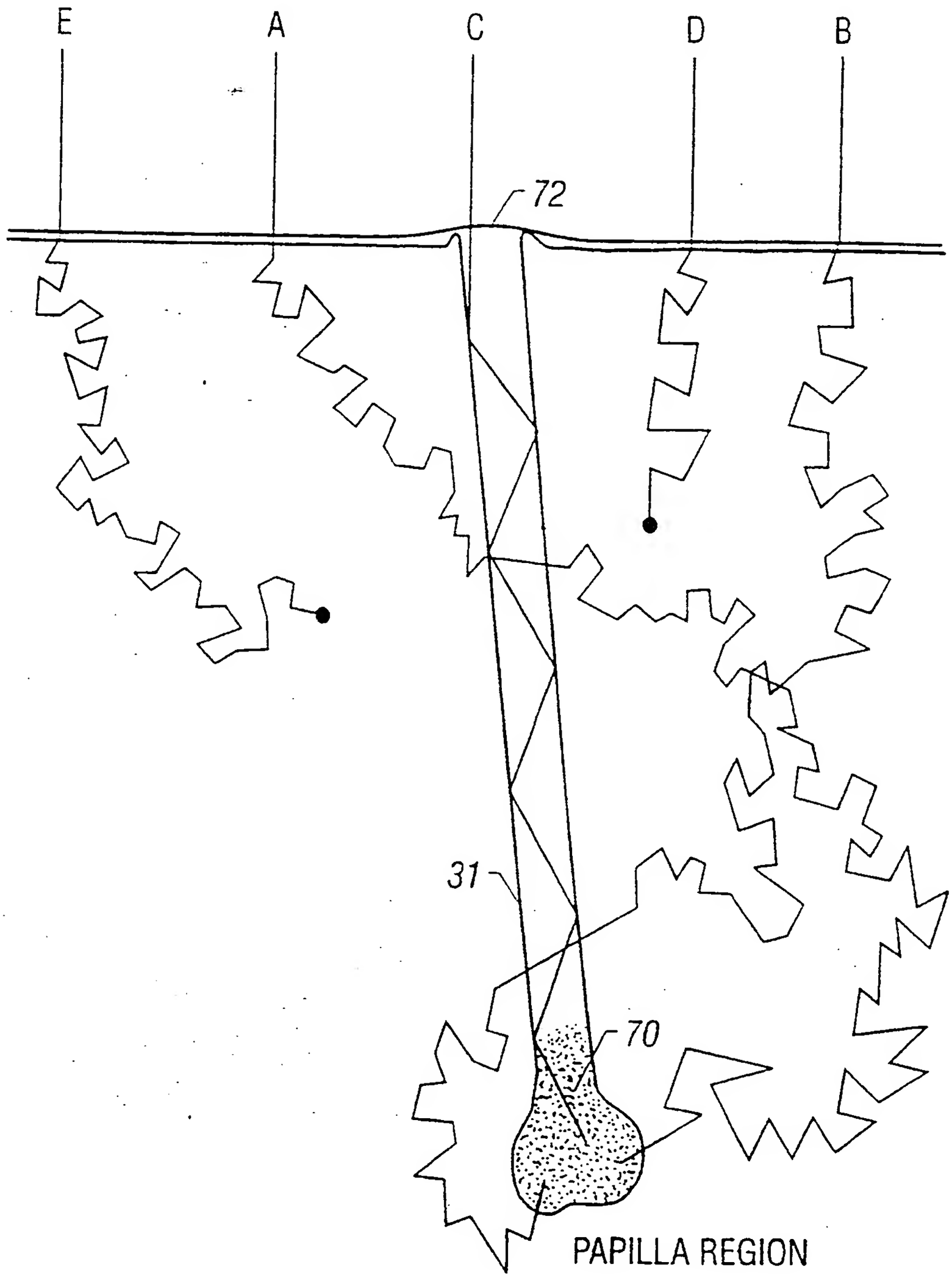


FIG. 6

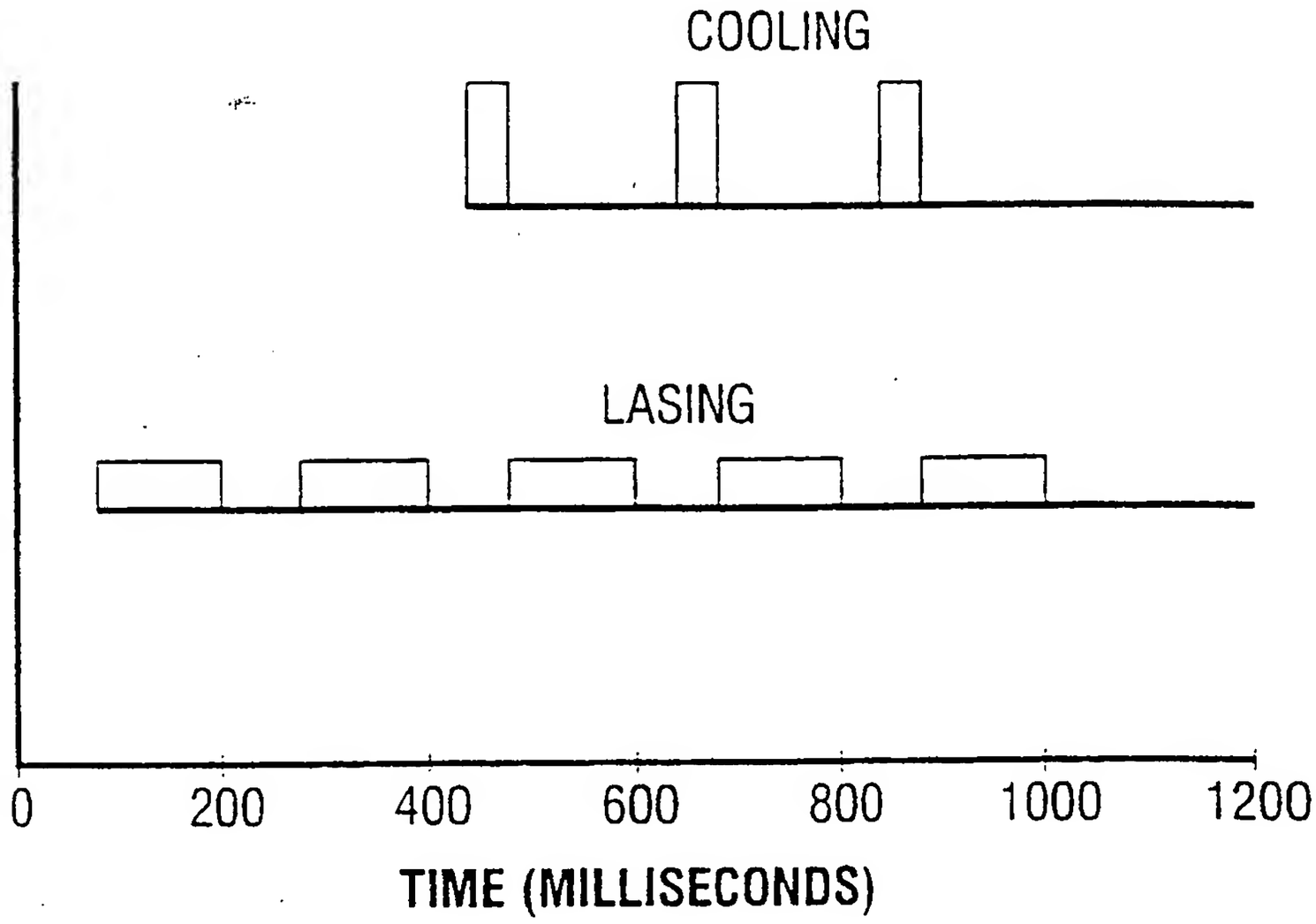

COOLING
LASING
0
200
400
600
800
1000
1200
TIME (MILLISECONDS)

FIG. 7

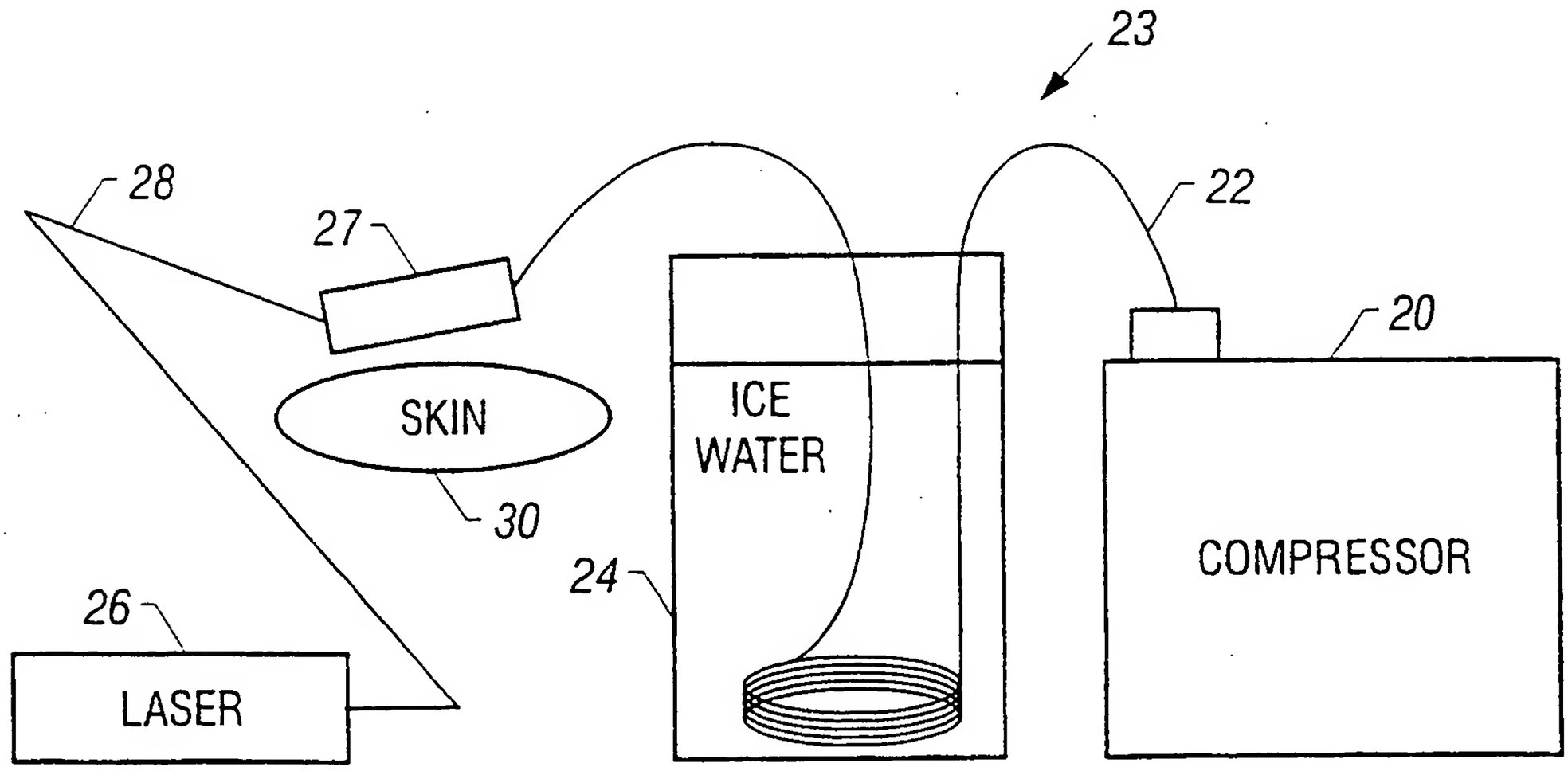

23
28
27
22
SKIN
ICE
WATER
20
COMPRESSOR
30
24
26
LASER

FIG. 8

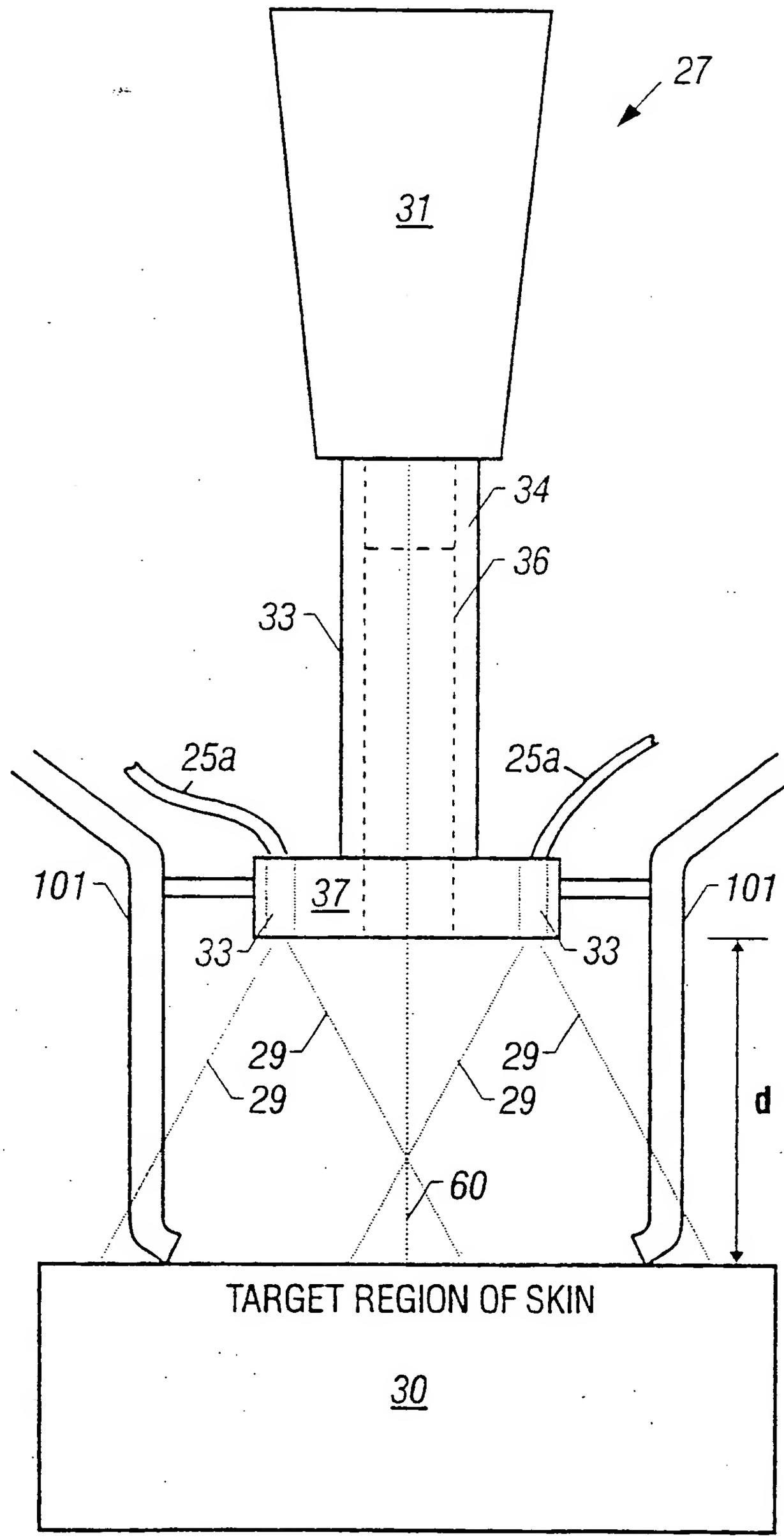

27
31
34
36
33
25a
25a
101
37
101
33
33
29
29
29
29
d
60
TARGET REGION OF SKIN
30

FIG. 9

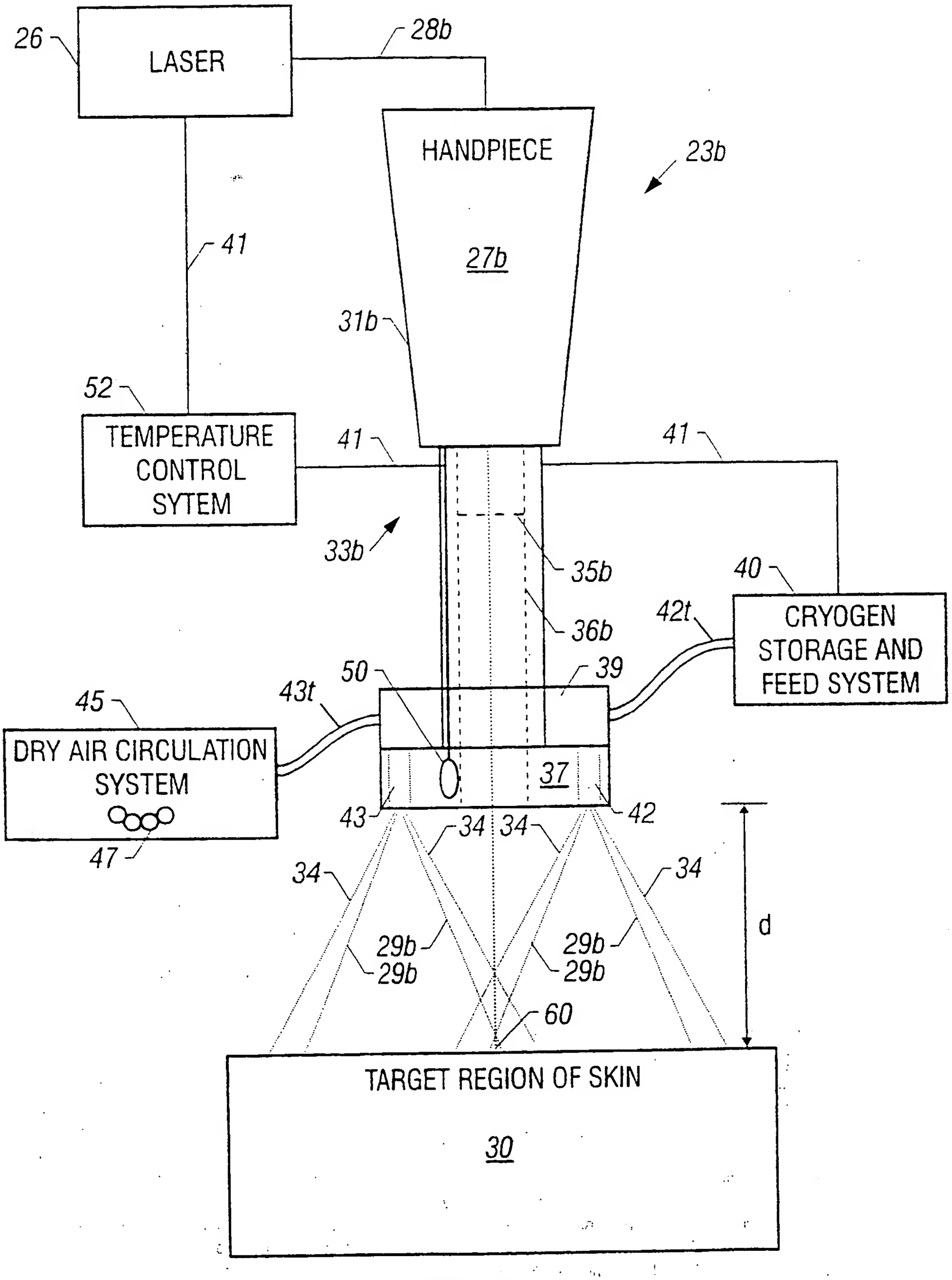

26
LASER
28b
HANDPIECE
23b
27b
31b
41
52
TEMPERATURE CONTROL SYTEM
41
41
33b
35b
36b
40
42t
CRYOGEN STORAGE AND FEED SYSTEM
50
39
43t
45
DRY AIR CIRCULATION SYSTEM
37
43
42
34
34
34
34
47
d
29b
29b
29b
29b
60
TARGET REGION OF SKIN
30

FIG. 10

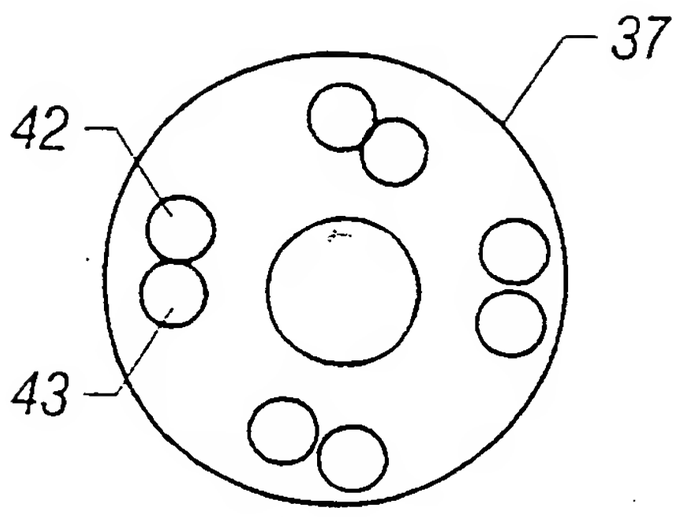


FIG. 11

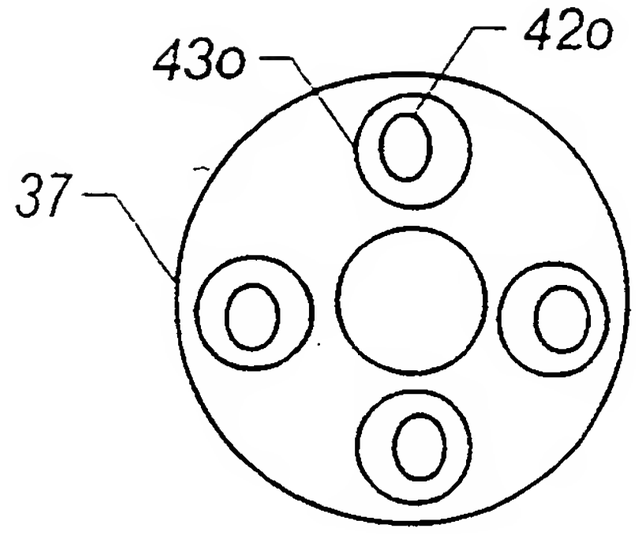


FIG. 12

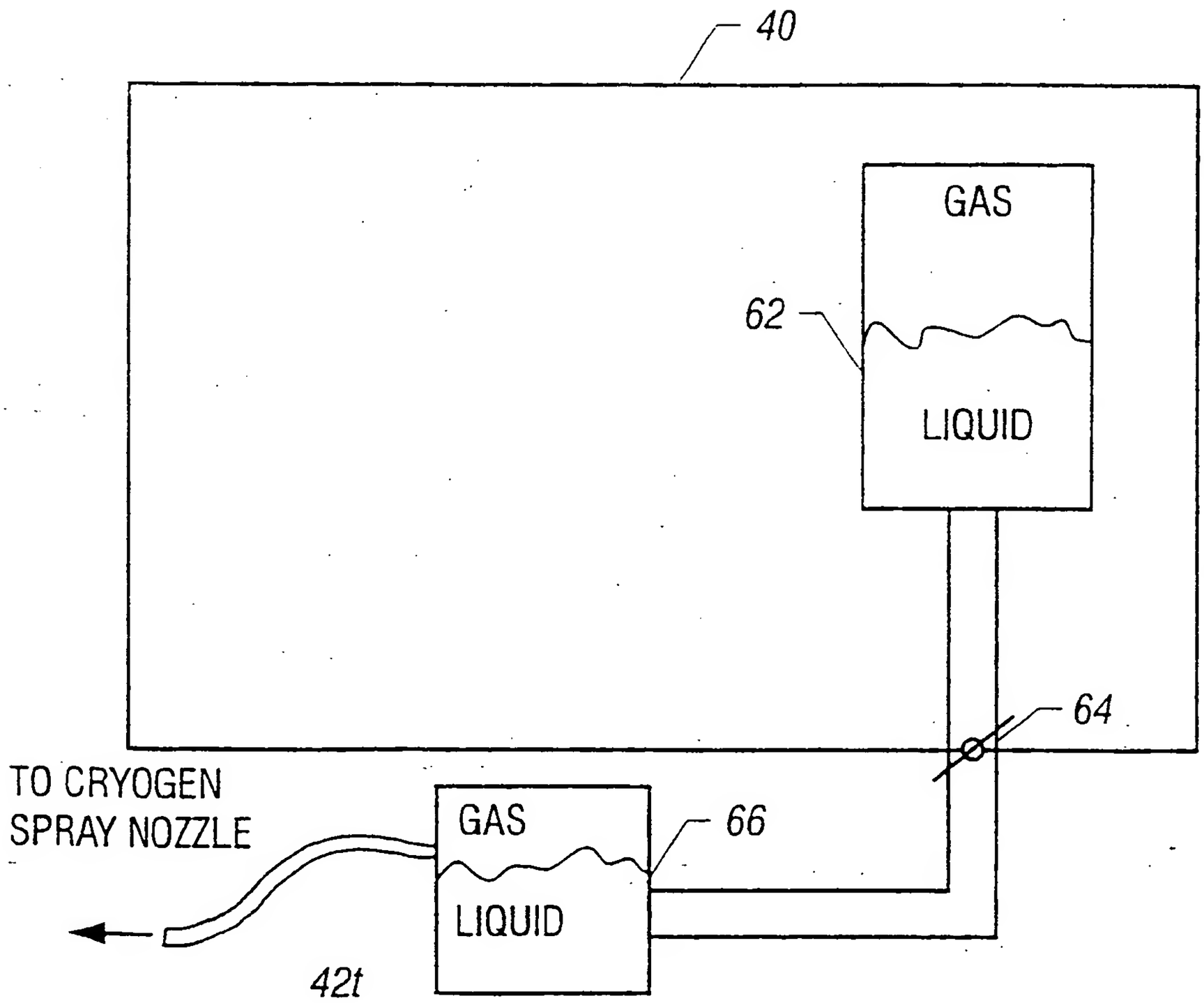


FIG. 13

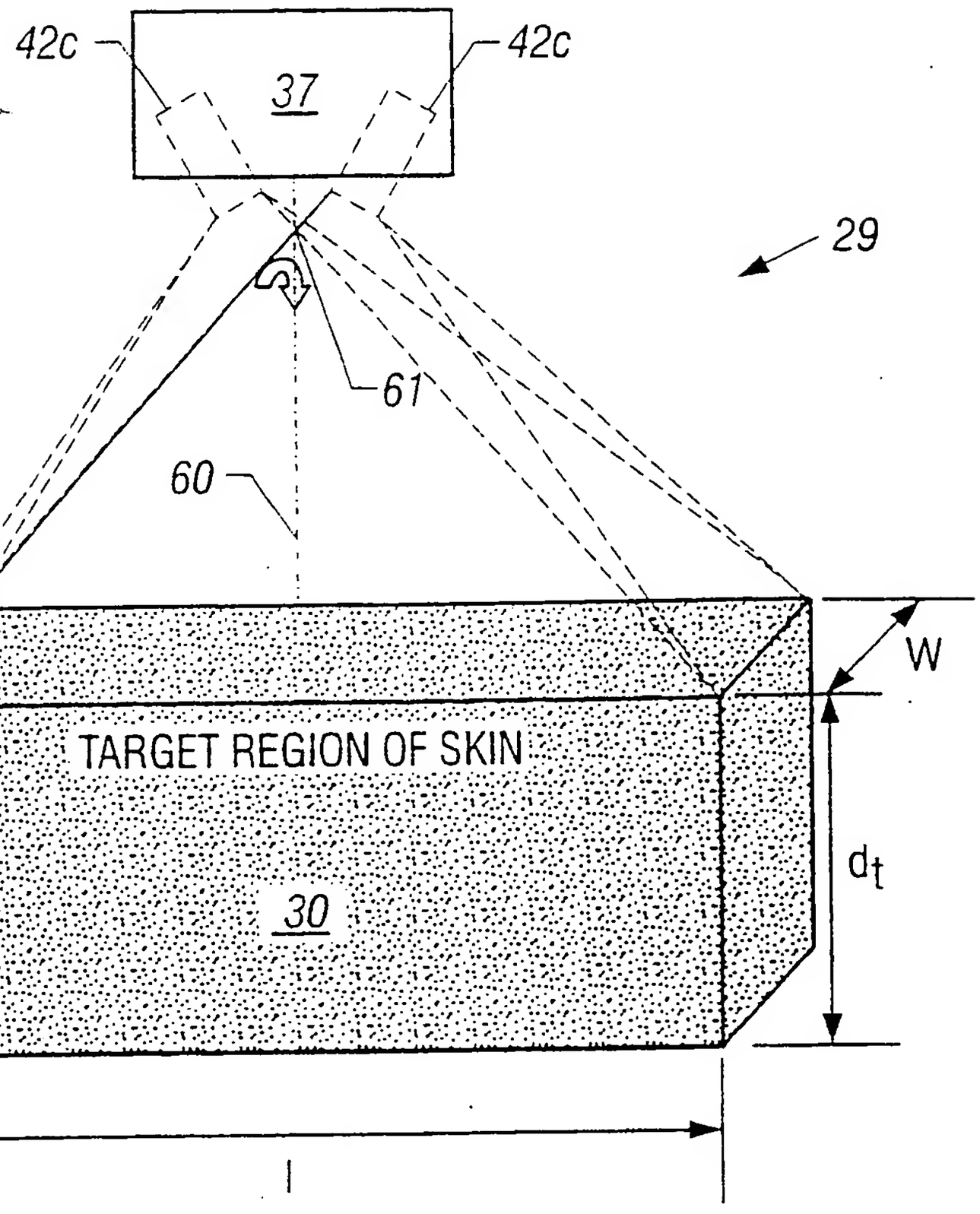


FIG. 14

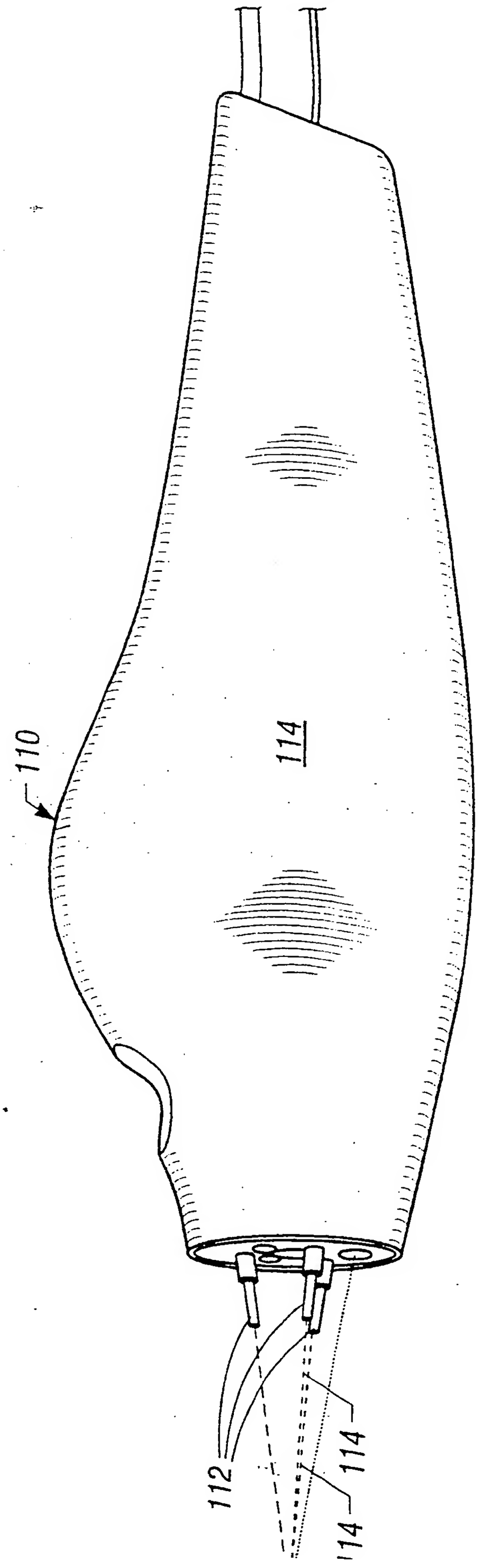


FIG. 15

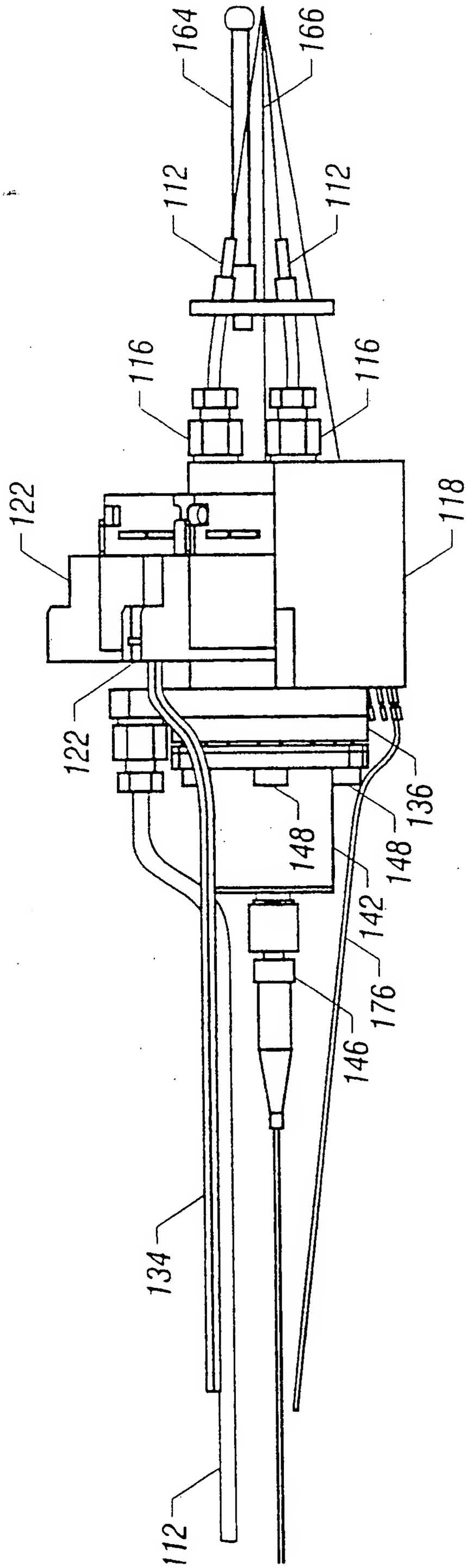

164
166
112
112
116
116
122
118
122
136
148
148
142
176
146
134
112

FIG. 16

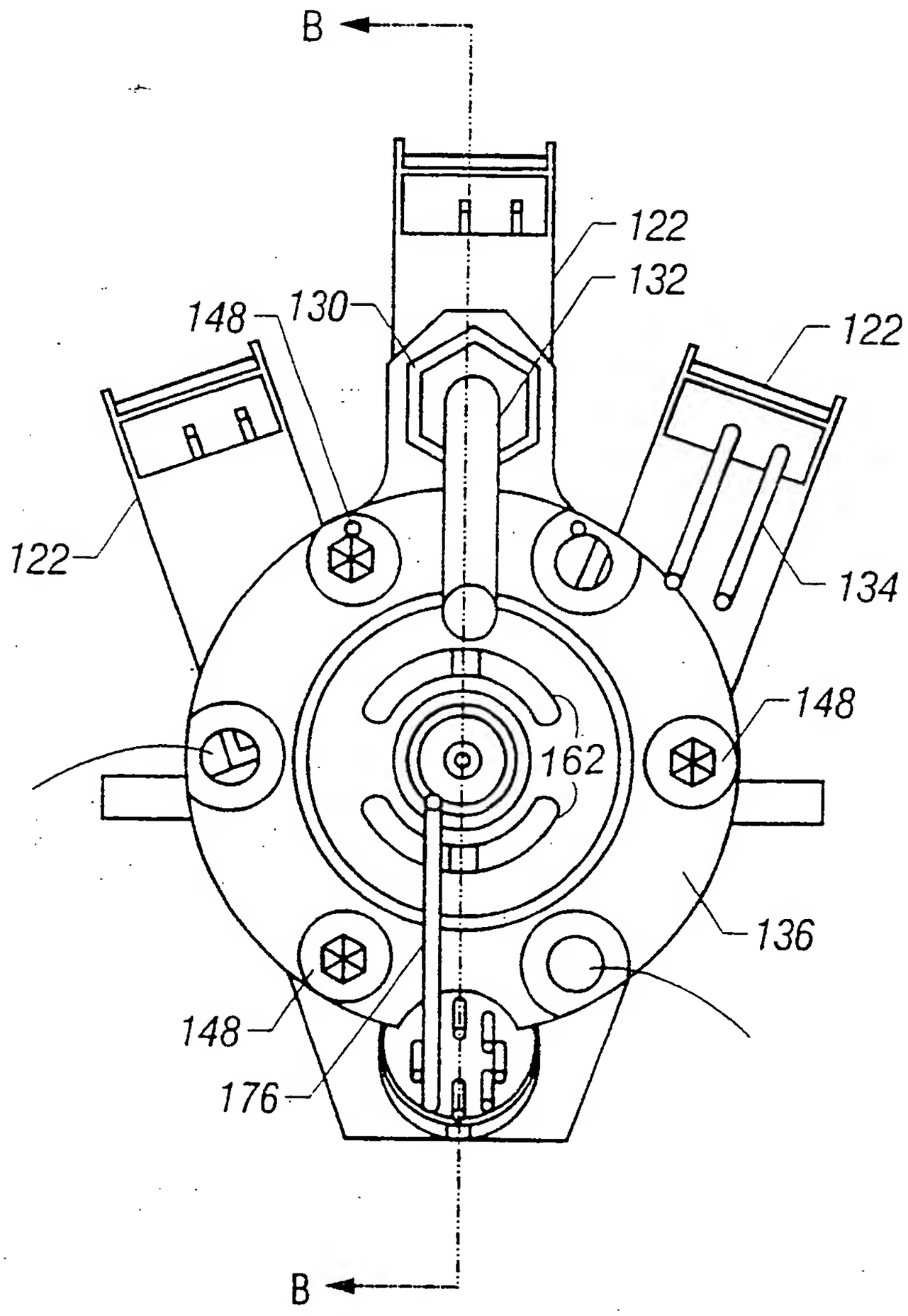


FIG. 17

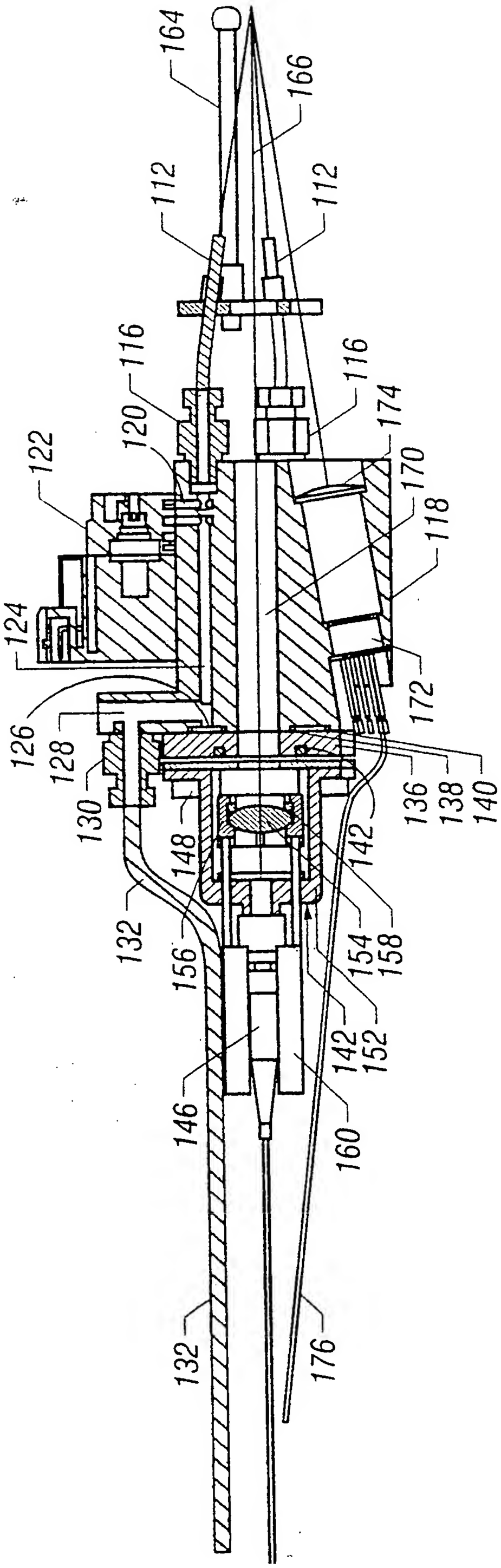

164
166
112
112
116
116
120
174
122
170
118
124
172
126
128
130
136
138
140
148
142
132
154
158
156
142
152
146
160
132
176

FIG. 18

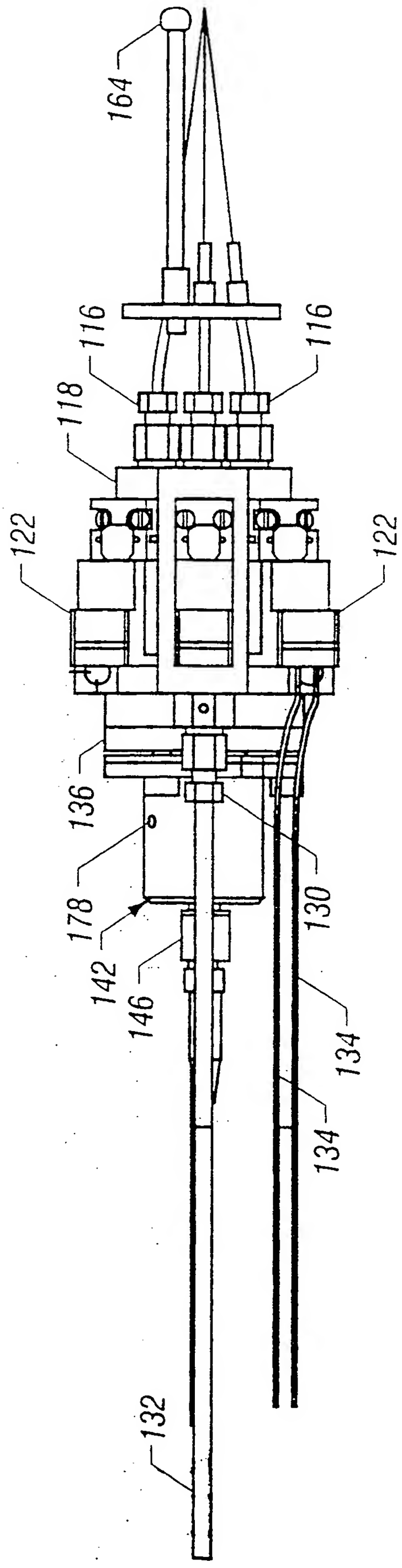


FIG. 19

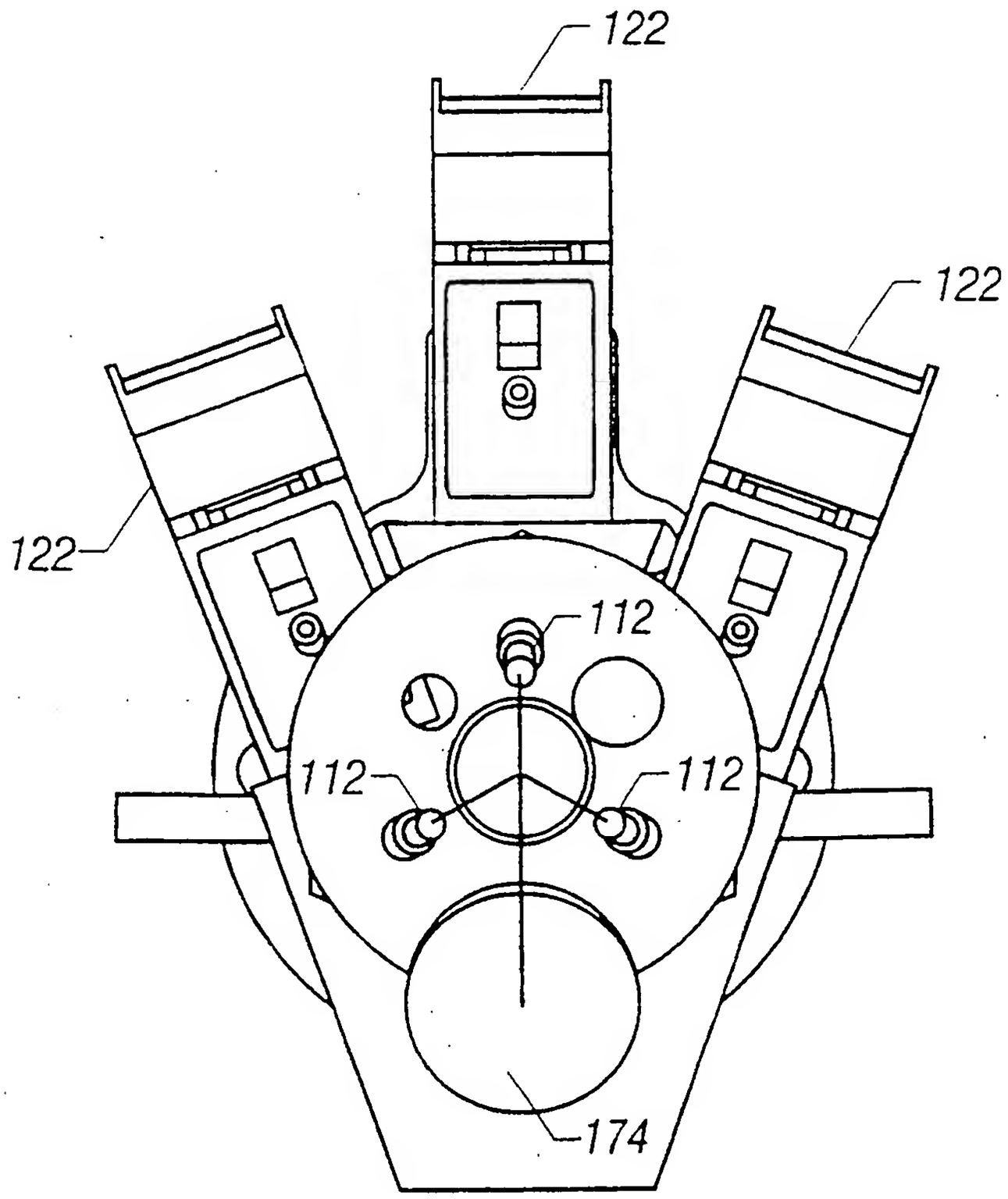


FIG. 20

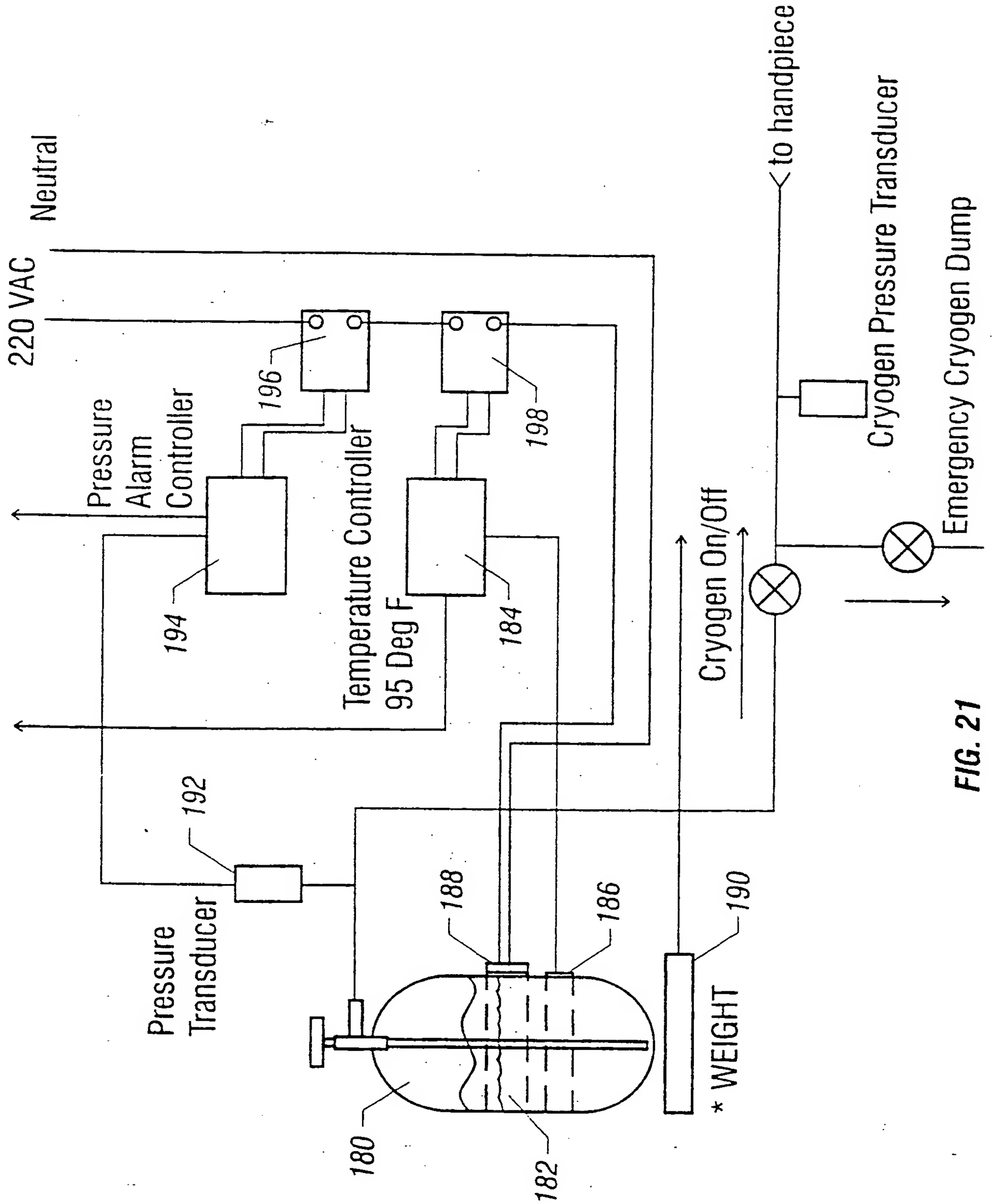

220 VAC
Neutral
Pressure Alarm Controller
194
196
Temperature Controller 95 Deg F
184
198
192
Pressure Transducer
188
186
190
180
182
* WEIGHT
Cryogen On/Off
to handpiece
Cryogen Pressure Transducer
Emergency Cryogen Dump

FIG. 21

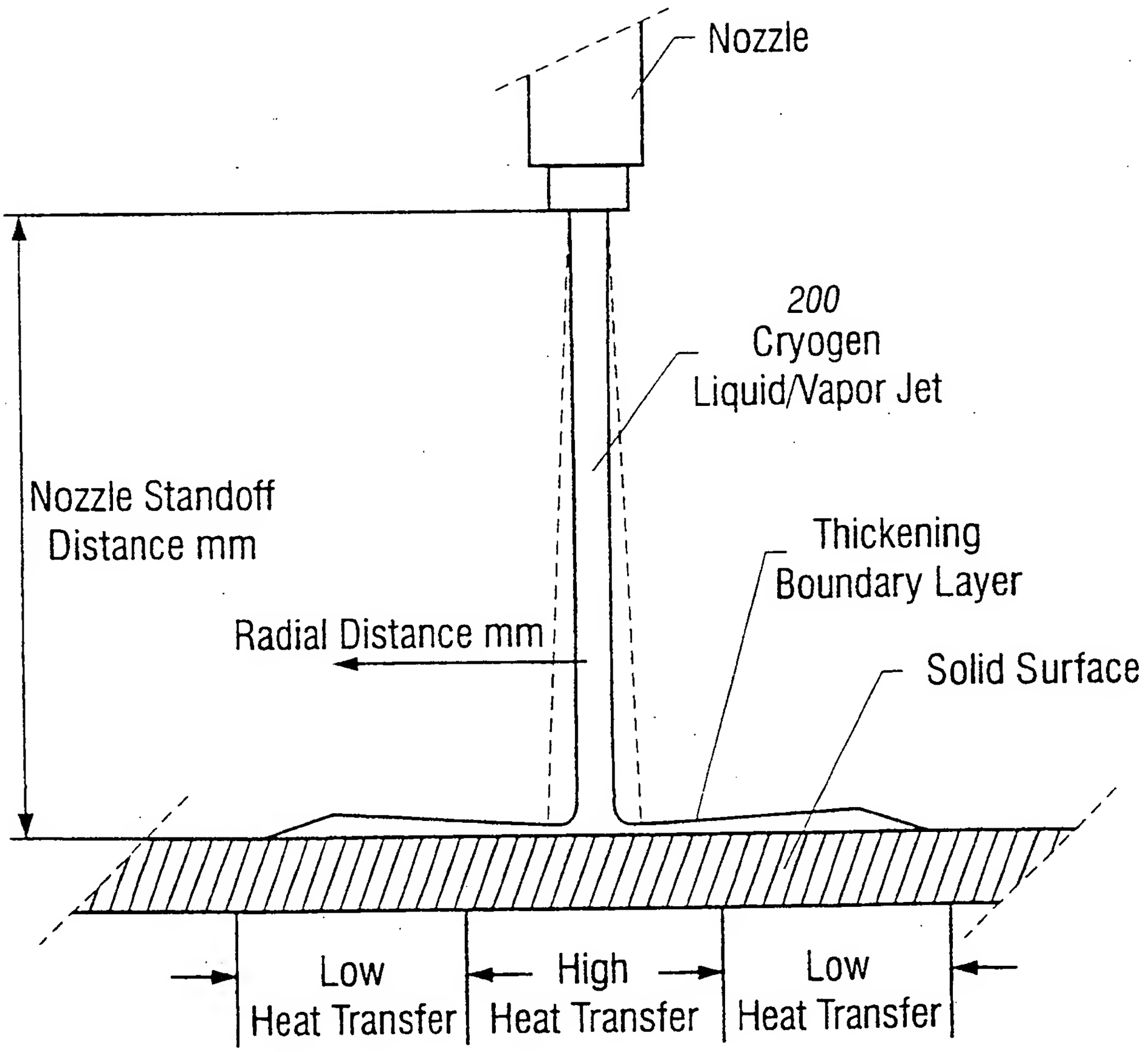

Nozzle
200
Cryogen
Liquid/Vapor Jet
Nozzle Standoff
Distance mm
Radial Distance mm
Thickening
Boundary Layer
Solid Surface
Low
Heat Transfer
High
Heat Transfer
Low
Heat Transfer

FIG. 22

INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/US 98/25827

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/41

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 195 12 481 A (UNIV CALIFORNIA) 12 October 1995 see page 4, line 21 - page 5, line 33; figure 3 ---	1,3,4
A	US 5 630 811 A (MILLER IAIN D) 20 May 1997 see column 10, line 33 - line 63; figure 6 ---	1
A	US 5 057 104 A (CHESS CYRUS) 15 October 1991 see column 4, line 17 - line 44; figure 1 ---	1
A	WO 97 00098 A (SVERDRUP LAWRENCE ;TANKOVICH NIKOLAI (US); THERMOLASE CORP (US); E) 3 January 1997 see abstract -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 March 1999	22/03/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hansen, S

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 98/25827

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19512481 A	12-10-1995	JP 8317933 A	03-12-1996
		US 5814040 A	29-09-1998
US 5630811 A	20-05-1997	CA 2222222 A	02-10-1997
		EP 0830090 A	25-03-1998
		WO 9735526 A	02-10-1997
		US 5853407 A	29-12-1998
US 5057104 A	15-10-1991	US 5486172 A	23-01-1996
		US 5282797 A	01-02-1994
WO 9700098 A	03-01-1997	US 5752948 A	19-05-1998
		US 5752949 A	19-05-1998
		AU 6336896 A	15-01-1997
		NZ 311947 A	28-01-1998
		AU 2940397 A	05-12-1997
		WO 9742849 A	20-11-1997